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FEDERAL ELECTION COMMISSION

11 CFR Parts 100, 104, 110, and 113

[Notice 2004–16]

Technical Amendments to Bipartisan Campaign Reform Act (''BCRA'') Rules and Explanation and Justification

AGENCY: Federal Election Commission.

ACTION: Final rule; technical amendments.

SUMMARY: The Commission is making technical amendments to correct certain citations and headings in the BCRA final rules governing the definitions of ''contribution'' and ''expenditure,'' personal use of campaign funds, and reporting. Corrections are also being made to the explanation and justification for the BCRA rules on disclaimers and personal use of campaign funds. Further information is provided in the supplementary information that follows.

DATES: *Effective Date:* November 24, 2004.

FOR FURTHER INFORMATION CONTACT: Mr. Brad C. Deutsch, Assistant General Counsel, or Ms. Cheryl A.F. Hemsley, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The final rules and the explanation and justification that are the subject of these corrections were published as part of a continuing series of regulations the Commission promulgated implementing the Bipartisan Campaign Reform Act of 2002 (Pub. L. 107–155, 116 Stat. 81 (March 27, 2002)) (''BCRA''). Because these corrections are merely technical and nonsubstantive, they are not a substantive rule requiring notice and comment under the Administrative Procedure Act, 5 U.S.C. 553. Under the ''good cause'' exception to the notice and comment requirements, 5 U.S.C. 553(b)(B) and 553(d)(3), the final rules are effective upon publication. Thus the corrected final rules are effective November 24, 2004.

I. Corrections to BCRA Rules in Title 11 of the Code of Federal Regulations

A. Correction to 11 CFR 100.77

The Commission is correcting two citations containing typographical errors in this section. Specifically, the references to §§ 100.65 and 100.66 were erroneous and are being changed to §§ 100.75 and 100.76, respectively.

B. Correction to 11 CFR 100.89

The Commission is correcting the title of this section. Specifically, a parenthetical contained in the title erroneously referred to a '' 'coattails' exception.'' This parenthetical is being removed.

C. Correction to 11 CFR 100.149

The Commission is correcting the title of this section. Specifically, a parenthetical contained in the title erroneously referred to a '' 'coattails' exception.'' This parenthetical is being removed.

D. Correction to 11 CFR 104.5

The Commission is correcting two citations containing typographical errors in section 104.5(c)(3)(ii). Specifically, the references to paragraphs (a)(1)(i) and (a)(1)(ii) were erroneous and are being changed to paragraphs (a)(1)(ii) and (a)(1)(iii), respectively.

E. Correction to 11 CFR Part 113

The title to 11 CFR part 113 is also being corrected. On December 13, 2002, the title of 11 CFR part 113 was changed to reflect the new post-BCRA regulations therein, *i.e.*, ''Use of Campaign Accounts for Non-Campaign Purposes.'' 67 FR 76962. However, on December 26, 2002, the title of part 113 was inadvertently changed back to its pre-BCRA wording, *i.e.*, ''Excess Campaign Funds and Funds Donated to Support Federal Officeholder Activities.'' Accordingly, the Commission is now restoring the correct wording of the title.

II. Corrections to BCRA Explanation and Justification Regarding Disclaimers and Personal Use of Campaign Funds

The Commission published a document in the **Federal Register** of December 13, 2002, at 67 FR 76962, containing final rules relating to disclaimers, fraudulent solicitations, civil penalties, and personal use of campaign funds. The portions of the explanation and justification regarding disclaimers and personal use of campaign funds contained (1) an instance of erroneous language, (2) an erroneous reference and (3) an erroneous omission, each of which is being corrected, as discussed below.

A. Correction to Explanation and Justification for 11 CFR 110.11—Communications; Advertising; Disclaimers

The published explanation and justification for 11 CFR 110.11(c)(4), concerning radio and television communications, mistakenly included two sentences referring to a disclaimer for communications transmitted through a telephone bank. *See* 67 FR at 76967. Accordingly, these sentences are being removed.

Specifically, on page 76967, 67 FR at 76967, second column, the following two sentences are being removed from lines twenty-four through thirty-four: ''Paragraph (c)(4) also requires that communications transmitted through a telephone bank, as defined in 11 CFR 100.28, carry the same statement. *See* discussion regarding the inclusion of telephone banks within the term 'public communication,' above, and the discussion of specific requirements for radio, telephone bank, and television communications authorized by candidates, above.''

B. Correction to Explanation and Justification for 11 CFR Part 113—Use of Campaign Accounts for Non-Campaign Purposes

Two corrections to the published explanation and justification for 11 CFR part 113 are necessary.

First, the published explanation and justification erroneously referred to a portion of the pre-BCRA title of part 113 in describing the title change being effected in the corresponding regulations. *See* 67 FR at 76971. Accordingly, the reference to the title of part 113 is being corrected to reflect the post-BCRA wording. Specifically, on page 76971, first column, lines nineteen through twenty-one, the reference to ''Campaign Funds and Funds Donated to Support Federal Officeholder Activities'' is being corrected to read

''Use of Campaign Accounts for Non-Campaign Purposes.''

Second, although the text of the explanation and justification approved by the Commission stated that ''Authorized committees may not make contributions * * *'' (emphasis added), the published explanation and justification erroneously omitted the word ''not'' from this sentence. *See* 67 FR at 76975. Accordingly, this sentence is being corrected to include the omitted word.

Specifically, on page 76975, second column, lines three through ten, the sentence ''Authorized committees may make contributions to organizations other than those described in section 170(c) of the Internal Revenue Code of 1986 and other authorized committees (subject to the $1,000 limit) unless those contributions are in connection with the campaign for Federal office of the authorizing candidate'' is being corrected to read ''Authorized committees may not make contributions to organizations other than those described in section 170(c) of the Internal Revenue Code of 1986 and other authorized committees (subject to the $1,000 limit) unless those contributions are in connection with the campaign for Federal office of the authorizing candidate.''

Correction of Publication

In FR Doc 02–31521, published on December 13, 2002 (67 FR 76962), make the following corrections.

1. On page 76967, in the second column, in line twenty-four, remove ''Paragraph (c)(4) also requires that communications transmitted through a telephone bank, as defined in 11 CFR 100.28, carry the same statement. *See* discussion regarding the inclusion of telephone banks within the term ''public communication,'' above, and the discussion of specific requirements for radio, telephone bank, and television communications authorized by candidates, above.''

2. On page 76971, in the first column, in line nineteen remove ''Campaign Funds and Funds Donated to Support Federal Officeholder Activities'' and add ''Use of Campaign Accounts for Non-Campaign Purposes'' in its place.

3. On page 76975, in the second column, in line three remove ''Authorized committees may make contributions to organizations other than those described in section 170(c) of the Internal Revenue Code of 1986 and other authorized committees (subject to the $1,000 limit) unless those contributions are in connection with the campaign for Federal office of the authorizing candidate'' and add ''Authorized committees may not make contributions to organizations other than those described in section 170(c) of the Internal Revenue Code of 1986 and other authorized committees (subject to the $1,000 limit) unless those contributions are in connection with the campaign for Federal office of the authorizing candidate'' in its place.

List of Subjects

11 CFR Part 100

Elections.

11 CFR Part 104

Campaign funds, political committees and parties, reporting and recordkeeping requirements.

11 CFR Part 110

Campaign funds, and political committees and parties.

11 CFR Part 113

Campaign funds.

■ For the reasons set out in the preamble, subchapter A of chapter I of title II of the *Code of Federal Regulations* is amended as follows:

PART 100—SCOPE AND DEFINITIONS (2 U.S.C. 431)

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 2 U.S.C. 431, 434, 438(a)(8).

■ 2. In the table below, for each section indicated in the left column, remove the citation indicated in the middle column, and replace it with the citation indicated in the right column:

Section	Remove	Add
100.77	100.65	100.75
100.77	100.66	100.76

■ 3. Section 100.89 is amended by revising the heading to read as follows:

§ 100.89 Voter registration and get-out-the-vote activities for Presidential candidates.

* * * * *

■ 4. Section 100.149 is amended by revising the heading to read as follows:

§ 100.149 Voter registration and get-out-the-vote activities for Presidential candidates.

* * * * *

PART 104—REPORTS BY POLITICAL COMMITTEES AND OTHER PERSONS (2 U.S.C. 434)

■ 5. The authority citation for part 104 continues to read as follows:

Authority: 2 U.S.C. 431(1), 431(8), 431(9), 432(i), 434, 438(a)(8) and (b), 439a, 441a, and 36 U.S.C. 510.

■ 6. In the table below, for each section indicated in the left column, remove the citation indicated in the middle column, and replace it with the citation indicated in the right column:

Section	Remove	Add
104.5(c)(3)(ii)	104.5(a)(1)(i)	104.5(a)(1)(ii)
104.5(c)(3)(ii)	104.5(a)(1)(ii)	104.5(a)(1)(iii)

PART 113—USE OF CAMPAIGN ACCOUNTS FOR NON-CAMPAIGN PURPOSES

■ 7. Part 113 is amended by revising the heading to read as set forth above.

■ 8. The authority for part 113 continues to read as follows:

Authority: 2 U.S.C. 432(h), 438(a)(8), 439a, 441a.

Dated: November 19, 2004.

Bradley A. Smith,

Chairman, Federal Election Commission.

[FR Doc. 04–26042 Filed 11–23–04; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Parts 506, 516, 528, 543, 544, 545, 552, 559, 563, 563b, 567, 574, and 575

[No. 2004–54]

RIN 1550–AB93

EGRPRA Regulatory Review—Application and Reporting Requirements

AGENCY: Office of Thrift Supervision, Treasury (OTS).

ACTION: Interim final rule.

SUMMARY: As a part of its review of regulations under section 2222 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (Pub. L. 104–208, Sept. 30, 1996) (EGRPRA), the Office of Thrift Supervision (OTS) is reducing regulatory burden on savings associations by updating and revising various application and reporting requirements. Specifically, OTS is: (1) Modifying the branch office and agency office application and notice requirements, (2) harmonizing publication and public comment procedures for various applications and notices, and (3) revising the meeting procedures. OTS is also eliminating various obsolete rules.

Today's changes are designed to reduce burden to the extent consistent with safe and sound supervision of the industry. They further the burden reduction efforts in OTS's recently published proposed and final rules implementing the Community Reinvestment Act (CRA).

DATES: This rule is effective on January 1, 2005. Comments must be received by January 24, 2005.

ADDRESSES: You may submit comments, identified by No. 2004–54, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail address: regs.comments@ots.treas.gov*. Please include No. 2004–54 in the subject line of the message and include your name and telephone number in the message.
- *Fax:* (202) 906–6518.
- *Mail:* Regulation Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention: No. 2004–54.
- *Hand Delivery/Courier:* Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9 a.m. to 4 p.m. on business days, Attention: Regulation Comments, Chief Counsel's Office, Attention: No. 2004–54.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to the OTS Internet Site at *http://www.ots.treas.gov/pagehtml.cfm?catNumber=67&an=1*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.ots.treas.gov/pagehtml.cfm?catNumber=67&an=1*. In addition, you may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment for access, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755. (Prior notice identifying the materials you will be requesting will assist us in serving you.) We schedule appointments on business days between 10 a.m. and 4 p.m. In most cases, appointments will be available the next business day following the date we receive a request.

FOR FURTHER INFORMATION CONTACT: Josephine Battle, Program Analyst, Thrift Policy, (202) 906–6870; Donald Dwyer, Director, Applications, Examinations and Supervision Operations, (202) 906–6414; Karen Osterloh, Special Counsel, Regulations and Legislation Division, (202) 906–6639; or Gary Jeffers, Senior Attorney, Business Transactions Division, (202) 906–6457, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2003, OTS and the other Federal banking agencies began a joint effort to review their rules and identify outdated or otherwise unnecessary regulatory requirements. This review is required by section 2222 of EGRPRA, which directs the banking agencies to jointly or individually categorize their regulations by type, provide notice and solicit public comment on the categories, request commenters to identify areas of the regulations that are outdated, unnecessary, or unduly burdensome, and eliminate unnecessary regulations to the extent that such action is appropriate. 12 U.S.C. 3311. As part of this EGRPRA process, OTS, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation (FDIC), and the Office of the Comptroller of the Currency published a notice seeking comment on unnecessary regulatory burden in their rules governing application and reporting requirements.[1]

Based on the comments submitted in response to the notice and additional comments voiced at EGRPRA outreach meetings, OTS is making various changes to its application and reporting requirements. These changes are designed to reduce burden to the extent consistent with the safe and sound supervision of the industry. They further the burden reduction efforts that OTS began in its final rule published in the **Federal Register** on August 18, 2004, which revised the definition of ''small savings association'' used in the CRA regulations. 69 FR 51155. They also complement the burden reductions contained in the proposed CRA rule published elsewhere in today's **Federal Register**. The related proposed CRA rule would revise the definition of ''community development'' to encourage savings associations to increase community development services in rural areas, and would provide additional flexibility in the assignment of CRA ratings to permit large retail savings associations to focus their community reinvestment efforts on activities needed by their communities.

Specifically, today's final rule: (1) Modifies the branch office and agency office application and notice requirements, (2) harmonizes publication and public comment procedures for various applications and notices, and (3) revises the meeting procedures. OTS is also eliminating various obsolete rules. These changes are discussed below.

II. Interim Final Rule

A. Branch and Home Offices

As part of the EGRPRA process, OTS reviewed the application requirements that apply to branch and home offices operated by Federal savings associations. Currently, OTS requires a Federal savings association to file an application or notice when it establishes a new branch office, changes the permanent location of an existing home or branch office, or changes the designation of an office as a home or branch office.[2] OTS permits a Federal savings association to change the

[1] 68 FR 35589 (June 16, 2003). The June 2003 notice also addressed powers and activities and international operations. In January 2004, the agencies published a second notice seeking comment on consumer protection provisions in lending-related rules. 69 FR 2852 (Jan. 21, 2004). In July 2004, the agencies published a third notice seeking comment on consumer protection provisions in other rules. 69 FR 43347 (July 20, 2004).

[2] 12 CFR 545.92, 545.93 and 545.95.

location of a home or branch office in a ''short-distance relocation'' without obtaining prior OTS approval. However, the association must notify OTS at least 30 days before the relocation to permit OTS to determine whether the proposed relocation satisfies all short-distance relocation requirements.[3] OTS does not require any branch application or notice for drive-in or pedestrian offices that meet certain requirements.[4]

Currently, State-chartered savings associations are not required to file any application or notice with OTS regarding changes to their home or branch offices. This has not raised any significant safety and soundness concerns for State-chartered savings associations. Accordingly, OTS has decided to modify its branch and home office application and notice requirements for Federal savings associations to ease regulatory burden to the extent feasible. OTS has made the following changes.

Elimination of application and notice requirements for re-designations of home and branch offices. Under the existing rules, a Federal savings association must file an application or notice and receive OTS prior approval before it re-designates a home office or branch office.[5] Because office re-designations do not raise significant supervisory or compliance issues, today's interim final rule eliminates this requirement. To ensure that OTS has the current addresses of all home offices, however, the home office rule requires Federal savings associations to notify their appropriate OTS Regional Offices if the permanent address of its home office changes.

Elimination of application and notice requirements for certain highly rated Federal savings associations. Under the interim final rule, certain highly rated Federal savings associations will be permitted to change the location of a home or branch office or establish a new branch office without filing an application or notice with OTS. Under this exception, a Federal savings association is not required to submit an application or notice if it satisfies all of the following criteria:

- Its composite rating under the Uniform Financial Institutions Rating Systems (CAMELS) was 1 or 2 during the most recent examination.
- Its CRA rating was satisfactory or outstanding during the most recent examination.
- Its compliance rating was 1 or 2 during the most recent examination.
- It satisfies all of its capital requirements under 12 CFR part 567. The Federal savings association must meet this standard both before and immediately following the establishment or relocation of the office.
- OTS has not notified the Federal savings association that it is in troubled condition.[6]

OTS believes that these standards will ensure that only those Federal savings associations that are operated in a safe and sound manner and consistent with applicable CRA and compliance requirements will be exempted from application and notice requirements.

To ensure that the public continues to be afforded an opportunity to comment on a Federal savings association's record of compliance with the CRA and other matters, OTS will require the association to solicit comment by publishing a newspaper notice indicating that it intends to change the location of a home or branch office or establish a new branch office.[7] If no commenter objects to the proposed action during a 30-day comment period following the publication, an application or notice will not be required. If a comment opposing the application is filed, the Federal savings association will be required to file an application or notice unless OTS determines that the comment raises issues that are not relevant to the branch and home office approval standards or determines that OTS action in response to the comment is not required.

OTS is considering imposing an additional condition on the use of this exception. Branch offices can be costly to build and operate. Moreover, excessive growth can present other supervisory issues. OTS regulations currently limit the amount of the book value of a Federal savings association's investment in real estate used for office and related facilities to the amount of its total capital.[8] OTS is concerned that this limitation may not be sufficient to ensure safe and sound operations. Accordingly, the final rule may require an application or notice if the savings association's investment in branch and home offices exceeds a specified limit, or the association is engaged in multiple branch expansions. OTS specifically requests comment on this point.

Elimination of notice requirement for short-distance relocations. As noted above, the current rules require a Federal savings association to notify OTS at least 30 days before a short-distance relocation of a home or branch office. OTS is eliminating this notice as overly burdensome. OTS has also updated the terminology used in this section to reflect U.S. Census Bureau usage.[9]

Compliance with section 5(m). Section 5(m)(1) of the Home Owners' Loan Act (HOLA) states:

(A) No savings association incorporated under the laws of the District of Columbia or organized in the District or doing business in the District shall establish any branch or move its principal office or any branch without the Director's prior written approval.

(B) No savings association shall establish any branch in the District of Columbia or move its principal office or any branch in the District without the Director's prior written approval.[10]

Because the existing regulations require OTS approval before a Federal savings association may establish a branch office or relocate a home or branch office, section 5(m) of the HOLA has not imposed any burden on Federal savings associations. There is no compelling reason to treat Federal savings associations in the District of Columbia differently from savings associations located elsewhere with respect to branch and home office applications. Accordingly, the Director of OTS is providing his prior written approval under section 5(m) to permit Federal savings associations incorporated under the laws of, organized in, or doing business in the District of Columbia to relocate home or branch offices and to establish branch offices, if the Federal savings association is eligible for the exceptions described in this section. OTS also plans to seek a legislative change eliminating section 5(m) of the HOLA as unnecessary.

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[3] 12 CFR 545.95(c).

[4] 12 CFR 545.92(g). In addition, an existing association that converts to a Federal savings association may maintain an existing office, and a Federal savings association that acquires offices through consolidation, purchase of bulk assets, merger or purchase from a receiver of an association may maintain an acquired office, except to the extent that the OTS approval order specifies otherwise. 12 CFR 545.92(h). A separate branch application or notice is not required for these offices because OTS considers issues regarding these offices in connection with the conversion, consolidation, merger, or purchase application or notice.

[5] 12 CFR 545.95.

[6] These requirements are the same as those for expedited processing at 12 CFR 516.5.

[7] A Federal thrift must follow the publication requirements in part 516, subpart B of this chapter with certain modifications specified in the interim final rule. For example, because the thrift will not submit an application or notice to OTS for these offices, the interim final rule states that 12 CFR 516.55(g), which addresses public inspection of filings, does not apply.

[8] 12 CFR 560.37.

[9] The U.S. Census Bureau now uses the term ''principal city'' in lieu of ''central city.''

[10] 12 U.S.C. 1464(m)(1).

Other changes. OTS has made other changes that reduce regulatory burdens. For example, OTS has eliminated restrictions on the establishment of drive-in or pedestrian offices. Like the current rule, the interim final rule does not require an application or notice for a drive-in or pedestrian office that is within 500 feet of an approved branch or home office. The functions of the office must be limited to services that are ordinarily provided at a teller window. Under the current rule, a drive-in or pedestrian office requires prior OTS approval if a public entrance of another SAIF-insured association is closer to the drive-in or pedestrian window. OTS has eliminated this requirement as unnecessary.

OTS has also substantially reorganized and rewritten its rules on branch and home offices. The interim final rule:

- Retains the existing definition of branch office at § 545.92(a).
- Reiterates statutory limitations on the location of a home or branch office at § 545.92(b). These limitations include sections 5(r) and 10(e)(3) of the HOLA, and section 13(k)(4) of the Federal Deposit Insurance Act.[11] These limits are currently addressed in 12 CFR 545.93(a) and (b).
- Reiterates OTS's position on Federal preemption with respect to branching by Federal savings associations at § 545.92(c). Preemption is addressed in the current rules at 12 CFR 545.93(d).
- States the revised application and notice filing requirements at § 545.93.
- Consolidates the existing application and notice processing rules and approval standards at § 545.95. The current rules governing processing of branch and home office applications and notices are contained in three separate overlapping regulations. *See* 12 CFR 545.92(b)–(f), 545.93(c), and 545.95(a)–(b).

As noted above, the interim final rule restates the approval standards in the current rule. OTS considers several other issues in its review of these applications, including compliance with the National Historic Preservation Act and the National Environmental Policy Act. OTS is considering including these other factors in the final rule and specifically requests comment on this point.

While Federal savings associations will no longer be required to file applications and notices for many branch office changes, OTS and others will, nonetheless, continue to have access to information on branch offices. All savings associations annually must send branch office data to OTS. This data may be accessed on the OTS home page under Data and Research>Corporate Directory>Summary of Deposits (*www.ots.treas.gov/pagehtml.cfm?catNumber=25*). Internet users may search for office deposits by institution, State, county or city. As a result, the general public, regulators, and bankers may: (1) Find the branches nearest to their home or office; (2) Evaluate an institution's share of the deposits in a particular market area; and (3) Analyze deposit information on existing branches in a particular market. OTS also intends to revise its internal examination procedures to ensure that its branch and home office location information is accurate and ensure that associations comply with all branching restrictions contained in the HOLA and OTS regulations. In addition, OTS will encourage all Federal savings associations to consult with their appropriate regional office before they open or relocate any office for which a branch application or notice is not required.

B. Agency Offices

OTS has also reviewed its rules on agency offices to determine whether these rules impose any unnecessary regulatory burden. Under the current OTS rule, a Federal savings association may establish or maintain an agency office to service and originate (but not approve) loans and contracts; to manage or sell real estate owned by the Federal savings association; and to conduct fiduciary activities or activities ancillary to the association's fiduciary business.[12] A Federal savings association may conduct other activities at agency offices. However, it must obtain prior OTS approval before it may do so.[13]

Most requests for additional activities at agency offices involve the approval of loans and contracts. Because these requests have not presented supervisory concerns, OTS believes that it may eliminate the notice requirement for loan and contract approval at agency offices without impacting safety and soundness. Accordingly, the interim final rule at § 545.96(a) states that a Federal savings association may approve loans and contracts at agency offices. As a result, a Federal savings association is not required to seek OTS approval to conduct such activities at an agency office.

OTS requests comment on whether there are other activities that may be added to the listing of permissible agency office activities without impacting safety and soundness. Based on the public comments, OTS may include additional revisions addressing these activities in the final rule.

C. Application Processing

12 CFR part 516 sets out OTS procedures for processing applications, notices, and other filings. While part 516 prescribes uniform procedures applicable to most applications, it also recognizes that regulations for specific types of applications may prescribe different processing procedures and timeframes. *See* 12 CFR 516.1(b)(4) and (c).

Commenters on the EGRPRA review suggested that OTS review these different processing procedures and timeframes, and amend its rules to synchronize and harmonize these procedures to the extent possible to reduce confusion. The commenters specifically identified inconsistent publication and public comment procedures as problematic.

OTS agrees that it is appropriate to provide more consistency between the publication and public comment procedures for various filings. Based on its review of conflicting requirements, OTS is revising certain applications procedures.

1. Public Notice Requirements

Timing of publication. OTS requires applicants to publish a newspaper notice soliciting public comment on certain types of applications. Under the uniform application procedures at 12 CFR part 516, subpart B, an applicant must publish a newspaper notice no earlier than seven days before the filing of the application and no later than the date of filing of the application.[14] By contrast, OTS regulations governing applications for conversions from mutual to stock form and change of control applications require an application to make its newspaper publication no earlier than three calendar days before, and no later than three calendar days after, filing of the application.[15] OTS is conforming the publication dates for the mutual to stock conversion rules and the change of control rules to the publication requirements for other applications.

Number of publications. OTS also reviewed whether it may make the number of required newspaper publications more consistent for OTS applications. OTS existing rules require a one-time newspaper publication for

[11] 12 U.S.C. 1464(r), 1467a(e)(3), and 1823(k)(4).

[12] 12 CFR 545.96(a).

[13] 12 CFR 545.96(b).

[14] 12 CFR 516.60.

[15] 12 CFR 563b.180(a) and 574.6(d).

most applications.[16] Regulations governing applications filed under the Bank Merger Act (BMA), however, provide for weekly publications over a 30-day period.[17]

Because the underlying BMA statute (12 U.S.C. 1828 (c)(3)) states that BMA notices must be published ''at appropriate intervals'' in a newspaper of general circulation, the only way to achieve a uniform requirement would be to require multiple notices for all applications. OTS believes that it would be unduly burdensome to make its rules consistent on this point and has retained the single publication requirement for all applications, except BMA applications.

2. Public Comment Procedures

Public comment period. Several EGRPRA commenters urged OTS to make the public comment period consistent for all applications. The comment period for most applications is 25 calendar days from the filing date of the application.[18] The comment period for a change of control application, however, is 20 days from the filing date. OTS may extend this period for an additional 20 days, for a total of 40 days.[19] The BMA rules at 12 CFR 563.22(e)(4) generally provide for a 30-day public comment period. This time period is prescribed by statute.[20] The mutual to stock conversion rules provide for a 20-day comment period.[21]

OTS has established a single comment period for all applications. OTS is establishing a standard public comment period of 30 days after the date of publication of the initial public notice. This change will provide greater uniformity in application processing, which was important to the commenters on the EGRPRA application.

Late-filed comments. The existing rules require OTS to consider a late-filed comment if certain requirements are met.[22] To provide OTS with sufficient flexibility to ensure the timely processing of applications, the interim final rule provides OTS with the discretion to consider a late-filed comment. Under the interim final rule, OTS will consider a late-filed comment only if it determines that the comment will assist in the disposition of the application.

3. Related Changes

In connection with the above changes, OTS reviewed the publication and comment procedures contained in the OTS Acquisition of Control Regulations at 12 CFR 574.6(d) and (e). These rules substantially duplicate the general application processing rules at 12 CFR part 516, subparts B and C. Rather than continue to restate these procedures in part 574, OTS is substituting appropriate cross-references to part 516, subparts B and C. This change will eliminate certain requirements regarding publication of notices. OTS believes that these requirements can be eliminated because they are unnecessarily burdensome or include materials that are best set out in OTS handbooks.[23] OTS has made similar revisions to the public notice and comment requirements in the mutual to stock conversion regulation in 12 CFR part 563b.

The interim final rule also clarifies that the procedures currently described in 12 CFR 563.22(e)(1) through (4) apply only to certain Bank Merger Act applications and restates these Bank Merger Act application procedures in plain language. Finally, the interim final rule deletes the public notice, public comment, and meeting procedures from the mutual holding company reorganization procedures at 12 CFR part 575. Instead, the rule clarifies that mutual holding company reorganizations under part 575 are subject to public notice, public comment and meeting requirements under the Bank Merger Act regulations at § 563.22(e)(1) and the Savings and Loan Holding Company Act regulations at § 574.6(d) and (e).

D. Application Processing—Formal and Informal Meetings

OTS rules at 12 CFR part 516, subpart D address informal and formal meetings held in connection with OTS applications. Under these rules, if a commenter requests a meeting, OTS must arrange an informal meeting to discuss issues raised in an application. OTS may conduct this informal meeting in any format, including a telephone conference or a face-to-face meeting. Following the informal meeting, an informal meeting participant may request a formal meeting. OTS must hold a formal meeting if requested.[24]

One commenter on the EGRPRA notice asserted that some commenters may request informal and formal meetings solely to delay the processing of an application. Moreover, in many situations commenters wish to raise facts and circumstances that are already known to OTS or raise issues that are only marginally related to the applicable approval criteria. To ensure that OTS is not required to conduct unnecessary meetings, the commenters urged OTS to conform its meeting procedures more closely to the procedures used by the other banking agencies. Specifically, the commenters urged OTS to revise its rules to require meetings only where there are material issues of fact.

Based on these considerations, OTS has revised its meeting procedures. The interim final rule eliminates the requirement that OTS must hold formal and informal meetings whenever a commenter makes a request for the meeting. Instead, the rule states that OTS will grant meeting requests only when it finds that written submissions are insufficient to address facts or issues raised by an application, or it otherwise determines that a meeting will benefit its decision-making process. OTS may limit the issues to be considered at the meeting to issues that OTS decides are relevant or material. The interim final rule continues to permit OTS to arrange a meeting on its own initiative.

If OTS decides to conduct a meeting, it will invite the applicant and any commenter that requested a meeting and raised an issue that OTS intends to consider at the meeting. OTS may also invite other interested persons to participate in the meeting. The interim final rule does not specify the procedures governing the conduct of meetings. Rather, to provide OTS with the maximum flexibility, the rule states that OTS may conduct a meeting in any format, such as a telephone conference,

[16] 12 CFR part 516, subpart B (application processing requirements in general) and 12 CFR 574.6(d) (change of control).

[17] 12 CFR 563.22(e)(1).

[18] 12 CFR 516.140.

[19] 12 CFR 574.6(e).

[20] 12 U.S.C. 1828(c)(3) states that the notice of the proposed transaction must be published during a period that is at least as long as the period allowed for the Attorney General and other federal banking agencies to furnish reports under 12 U.S.C. 1828(c)(4). This time period is generally 30 days, but can be 10 days if the agency advises the Attorney General and the other banking agencies that an emergency exists requiring expeditious action. The statute does not specify when the 30-day or 10-day time period commences. 12 U.S.C. 1828(c)(3).

[21] 12 CFR 563b.180.

[22] 12 CFR 516.140(b). OTS will consider a late-filed comment if: (1) Within the comment period, the commenter demonstrates to OTS good cause why the commenter could not submit a timely comment; or (2) OTS concludes that the comment addresses a significant regulatory concern and will assist in the disposition of the application.

[23] *E.g.*, 12 CFR 574.6(d)(1) (An acquiror must publish in the ''business section'' of a newspaper); 12 CFR 574.6(d)(2) (An acquiror must publish ''in a manner that is conspicuous to the average reader''); and 12 574.6(d)(2) (Acquirors must publish the notice substantially in the form set out in the regulations).

[24] 12 CFR 516.170 and 516.180.

face-to-face meeting, or a more formal meeting.

Under the current rules, if OTS decides to conduct a meeting, it must suspend applicable application processing time frames, including the time frames for deeming an application complete and the applicable approval time frames.[25] OTS has found that it is not always necessary to suspend applicable time frames when it conducts a meeting. To permit greater flexibility and prevent undue delay in processing applications, the rule provides OTS with discretion to suspend applicable time frames.

E. Other Changes

1. Section 528.4—Nondiscriminatory Advertising

Section 528.4 requires savings associations to include facsimiles of the equal housing lender logotype and legend in all advertising ''other than for savings.'' As a result, savings associations must include the logotype and legend in advertising for all types of lending, including lending that is unrelated to housing, such as credit card loans, commercial loans, and educational loans. By contrast, related rules issued by the other banking agencies require the display of the equal housing lender logotype and legend only with respect to advertisements for housing-related loans.[26]

OTS believes that its current requirement is too broad and imposes an unnecessary burden. Accordingly, OTS is amending § 528.4 to require displays of the equal housing logotype and legend only in advertisements for loans for the purpose of purchasing, constructing, improving, repairing, or maintaining a dwelling or loans secured by a dwelling.

2. Section 545.74—Securities Brokerage

12 CFR 545.74 addresses securities brokerage activities of service corporations. These requirements, which were originally promulgated in 1989, are largely obsolete, contain provisions that conflict with current law and guidance, and are confusing to the thrift industry. For example, this rule addresses third party brokerage arrangements between service corporations of Federal savings associations and broker-dealers to provide non-deposit investment products to customers. The Securities and Exchange Commission (SEC) requires such service corporations to register with SEC as broker-dealers. As a result, these service corporations are subject to investor protection and other rules issued by SEC and the National Association of Securities Dealers, which overlap with many provisions in the OTS regulation.[27]

Accordingly, in this interim rule, OTS is deleting existing § 545.74. OTS, however, is revising its pre-approved list of service corporation activities at § 559.4 to continue to permit service corporations to execute transactions in securities on an agency or riskless principal basis upon the order and for the accounts of customers and to provide investment advice, provided the service corporation registers with SEC or State securities regulators as required by applicable federal and state laws and regulations.[28]

3. Section 563.181—Reports of Change of Control of Mutual Savings Associations

In 1968, the Federal Home Loan Bank Board adopted a regulation requiring mutual savings associations to report changes in control as required under section 407 of the National Housing Act.[29] The regulation, which is currently codified at 12 CFR 563.181, has remained substantially unchanged since 1969. The underlying statute, however, was repealed in 1989.[30]

OTS does not believe that mutual associations should be required to routinely submit change of control reports. Changes in control of mutual associations are rare and OTS believes that its existing supervisory procedures are sufficient to identify when such a change does occur without requiring a mutual association to submit a report. Accordingly, OTS has deleted § 563.181 as unnecessary.

4. Section 563.183—Reports of Change in Chief Executive Officer or Director

Existing § 563.183 requires savings associations and savings and loan holding companies to report changes of chief executive officers and directors if the change occurs within 60 days before or 12 months after a change of control. This rule implements a statutory requirement at 12 U.S.C. 1817(j)(12). OTS believes that this statutory provision is outdated and should be eliminated, and will seek the legislative repeal of this requirement.

In the interim, OTS has decided to delete 12 CFR 563.183 and rely solely on the statutory requirement. This action will reduce burden in two ways. First, savings and loan holding companies will not be required to report changes of chief executive officers or directors. The statute requires reports only from savings associations. Second, this action eliminates the regulatory reporting requirement when a change of officer or director occurs within 60 days before a change of control. The statute only addresses changes of officers or directors that occur within 12 months after a change of control.

5. Section 567.13—Obligation of Acquirors of Savings Associations To Maintain Capital

Under 12 CFR 567.13, a person or company that controls a savings association and that is subject to a capital maintenance obligation, must notify OTS before it divests control of the thrift. Upon the receipt of notice, OTS will conduct an examination to determine whether there is a capital deficiency. If there is a deficiency, the person or company may not divest control of the savings association unless it pays or guarantees payment of the deficiency.

OTS has deleted this rule as obsolete. OTS no longer requires acquirors to execute capital maintenance agreements. Sufficient statutory and regulatory protections now exist to ensure that savings associations maintain adequate capital and to enable OTS to address capital deficiencies promptly and thoroughly.[31]

[25] 12 CFR 516.190.

[26] *Compare* 12 CFR 338.8 (FDIC).

[27] On July 11, 2003, OTS issued CEO Memorandum #178, which indicated that savings associations using a service corporation for networking arrangements should either replace the contract between the service corporation and the broker-dealer with a contract between the savings association and the broker-dealer, or register the service corporation as a broker-dealer.

[28] OTS has made an unrelated clarifying change to section 559.4(f)(3). This section specifically lists insurance brokerage or agency for liability, casualty, automobile, life, health, accident, or title insurance as a pre-approved activity for service corporations. Section 559.4(i) already permits service corporations to conduct activities on behalf of a customer on other than ''as principal'' basis. Since insurance brokerage and agency activities are subsumed within this new category, OTS deleted this duplicative reference. OTS emphasizes that this change does not, in any way, alter the pre-approved insurance activities of service corporations.

[29] 12 CFR 563.18–1, 33 FR 15277 (Oct. 15, 1968).

[30] Title IV of the National Housing Act, including section 407, was repealed in 1989. Pub. L. 101–73, Title IV, § 407, Aug. 9, 1989, 103 Stat. 363.

[31] Under the Prompt Corrective Action provisions of section 38 of FDICIA (12 U.S.C. 1831o(e)(2)(C)) and OTS implementing regulations (12 CFR 565.5), OTS may not approve a capital restoration plan for any ''undercapitalized'' institution unless each company that controls the institution: (1) Guarantees that the institution will comply with the plan until the institution has been adequately capitalized for four consecutive quarters; and (2) provides appropriate assurances of performance of the plan.

6. Miscellaneous Technical Revisions

OTS has included miscellaneous technical revisions in this rule. For example, the interim final rule updates cross-references to deleted or revised rules.

III. Regulatory Analysis

A. Administrative Procedure Act

Section 553 of the Administrative Procedure Act exempts rules of agency organization, procedure, and practice from notice and comment procedures. 5 U.S.C. 553. OTS finds that prior notice and public comment are not required to the extent that this rule: (1) Modifies publication requirements, public comment procedures, and meeting procedures that are used in the processing of applications and notices filed with OTS; (2) revises the application and notice requirements for branch and agency offices; and (3) eliminates obsolete reporting requirements.

The rule also eliminates obsolete rules that address securities brokerage activities by service corporations and capital maintenance obligations. OTS finds good cause for issuing these rule changes as an interim final rule. The continued inclusion of these provisions in the code of Federal regulations is confusing and likely to mislead the regulated entities. Accordingly, OTS finds that notice and public comment on these rule changes are impractical, unnecessary, and contrary to the public interest.

B. Plain Language Requirement

Section 722 of the Gramm-Leach-Bliley Act of 1999 requires federal banking agencies to use ''plain language'' in all proposed and final rules published after January 1, 2000. We invite your comments on how to make this rule easier to understand. For example:

(1) Have we organized the material to suit your needs?

(2) Are the requirements in the rule clearly stated?

(3) Does the rule contain technical language or jargon that isn't clear?

(4) Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?

(5) Would more (but shorter) sections be better?

(6) What else could we do to make the rule easier to understand?

C. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995, OTS may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. This interim final rule would continue to incorporate the information collection requirements contained in 12 CFR 543.2 and 552.2–1, currently approved under OMB Control No. 1550–0005, and does not make any material changes that affect the overall burden of compliance.

OTS also gives notice that the proposed revised collections of information—OMB Control Nos. 1550–0006, 1550–0011, 1550–0013, 1550–0014, 1550–0015, 1550–0016, 1550–0018, 1550–0056 and 1550–0072—were submitted to OMB for review and approval. At the end of the comment period, the comments and recommendations received will be analyzed to determine whether any of the information collections should be modified. Any material modifications will be submitted to OMB for review and approval. All comments will become a matter of public record.

Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Mark D. Menchik, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10236, New Executive Office Building, Washington, DC 20503, or e-mail to *mmenchik@omb.eop.gov;* and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov*. OTS will post comments and the related index on the OTS Internet Site at *http://www.ots.treas.gov*. In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *publicinfo@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755. To obtain a copy of the submission to OMB, contact Marilyn K. Burton at *marilyn.burton@ots.treas.gov*, (202) 906–6467, or facsimile number (202) 906–6518, Regulations and Legislation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of OTS's functions, including whether the information has practical utility;

(b) The accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

In this interim final rule, OTS is soliciting comments concerning the following information collections.

Branch Offices:

Title of Proposal: Branch Offices.

OMB Control No.: 1550–0006.

Form Number: OTS Forms 1450 and 1558.

Regulation Requirement: 12 CFR 545.93 and 545.95.

Affected Public: Savings associations.

Abstract: This interim rule revises, and under certain circumstances eliminates, the application and notice requirements for branch and home offices under 12 CFR 545.93 and 545.95. Revised 12 CFR §§ 545.93(a) and 545.95(a) require Federally-chartered institutions proposing to establish or change the location of a home or branch office to file an application or notice with OTS, unless one of the exceptions under § 545.93(b) applies. OTS analyzes each application or notice to ensure that there are no supervisory objections and that it meets all regulatory requirements. The remaining requirements in this information collection are unaffected by this interim rule, but are included in the overall burden estimate discussed below.

Estimated Number of Respondents: 897.[32]

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: Applications—2 hours; branch closing notices—.2 hours; recordkeeping (for policies required under the Interagency Branch Closing Policy Statement)—.25 hour; publication and posting—1 hour.

Estimated Total Burden: 484 hours.

[32] The estimate of 897 respondents refers to the number of institutions that will incur a recordkeeping burden for maintaining branch closing policies described in the Interagency Branch Closing Policy Statement. Based on the number of applications and notices received during the period October 21, 2003 through October 20, 2004, OTS estimates that, at most, 28 institutions will file applications or notices under § 545.95.

Agency Office:

Title of Proposal: General Reporting and Recordkeeping by Savings Associations: Agency Office.

OMB Control No.: 1550–0011.

Regulation Requirement: 12 CFR 545.96.

Affected Public: Savings associations.

Abstract: This interim final rule revises 12 CFR 545.96, which sets forth the guidelines for agency offices. This collection of information is part of a larger collection that covers general reporting and recordkeeping.

Estimated Number of Respondents: 20.

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: 1 hour.

Estimated Total Burden: 20 hours.

Securities Brokerage:

Title of Proposal: Request for Service Corporation Activity.

OMB Control No.: 1550–0013.

Form Number: OTS Form 1566.

Regulation Requirement: 12 CFR 559.3 and 559.12.

Affected Public: Savings associations.

Abstract: 12 CFR 545.74 addresses the authority of a service corporation of a Federal savings association to act as a broker or a dealer and to enter into third party brokerage arrangements, and includes various restrictions on these activities. This interim final rule continues to authorize such broker-dealer activities at § 559.4 but eliminates the OTS restrictions on these activities in existing § 545.74, thereby reducing burden in this information collection. The remaining requirements for this information collection are found at 12 CFR 559.12, which governs the issuance of securities. These requirements are otherwise unaffected by this rule, but are included in the overall burden estimates described below. These remaining requirements allow OTS to review service corporation activities and to ensure that they will not adversely affect an institution's safety and soundness.

Estimated Number of Respondents: 24 (preapproved activities); 4 (other activities).

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: .25 hours (preapproved activities); 2 hours (other activities).

Estimated Total Burden: 6 hours (preapproved activities); 8 hours (other activities)—14 hours total burden hours.

Mutual to Stock Conversion:

Title of Proposal: Application for Mutual to Stock Conversion.

OMB Control No.: 1550–0014.

Form Numbers: OTS Forms 1680, 1681, 1682, and 1683.

Regulation Requirement: 12 CFR part 563b.

Affected Public: Savings associations.

Abstract: Sections 5(i) (standard conversions) and 5(p) (supervisory conversions) of the Home Owners' Loan Act (HOLA) authorize mutual to stock conversions. 12 CFR part 563b governs mutual to stock conversions. This interim final rule revises the public notice and comment procedures for conversion applications. The remaining requirements in this information collection are unaffected by this interim rule, but are included in the overall burden estimates described below.

Estimated Number of Respondents: 7.

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: 510 hours.

Estimated Total Burden: 3,570 hours.

Savings Associations Holding Company Application:

Title of Proposal: Savings Associations Holding Company Application.

OMB Control No.: 1550–0015.

Form Number: Form H–(e).

Regulation Requirement: 12 CFR part 574.

Affected Public: Savings associations.

Abstract: Section 10(e) of the Home Owners' Loan Act (Act), as amended, and part 574 of the regulations promulgated thereunder provide that, unless a transaction is exempt under 12 CFR 574.3(c), no company or any director who owns, controls, or holds with power to vote (or holds proxies representing) more than 25 percent of the voting stock of a savings association holding company, may acquire control of a savings association without the prior written approval of OTS. This interim final rule revises certain procedural requirements found at § 574.6. The remaining requirements in this information collection are unaffected by this interim rule, but are included in the overall burden estimates discussed below.

Estimated Number of Respondents: 50.

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: 450 hours.

Estimated Total Burden: 22,500 hours.

Savings Associations—Operations:

Title of Proposal: Merger Applications.

OMB Control No.: 1550–0016.

Regulation Requirement: 12 CFR 563.22(a), 546, and 552.13.

Affected Public: Savings associations.

Abstract: OTS merger regulations are found at 12 CFR 563.22(a), and corporate governance requirements are found at 12 CFR part 546 and 12 CFR 552.13. This interim final rule revises and clarifies the requirements found at § 563.22(e) that apply to applications filed under § 563.22(a). The remaining requirements in this information collection are unaffected by this interim rule, but are included in the overall burden estimates discussed below.

Estimated Number of Respondents: 16.

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: 31 hours.

Estimated Total Burden: 496 hours.

Charter Amendments:

Title of Proposal: Amendment of Savings Association Charter.

OMB Control No.: 1550–0018.

Regulation Requirement: 12 CFR 544.2 and 552.4.

Affected Public: Savings associations.

Abstract: 12 CFR parts 544 and 552 require a federally chartered savings association to obtain agency approval of any changes in its charter that are not preapproved by regulation. This interim rule changes charter provisions addressing home office designations under 12 CFR 544.2(b)(3) and 552.4(b)(2). The remaining charter provisions covered by this information collection requirement are unaffected by this interim rule, but are included in the overall burden estimates discussed below.

Estimated Number of Respondents: 27.

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: 6 hours.

Estimated Total Burden: 162 hours.

Application Processing:

Title of Proposal: Application Filing Requirements.

OMB Control No.: 1550–0056.

Regulation Requirement: 12 CFR part 516.

Affected Public: Savings associations.

Abstract: OTS regulations require that applications, notices, or other filings must be submitted to the appropriate Regional Office of OTS, unless specifically noted otherwise in the procedures for a particular filing. OTS reviews applications for completeness and compliance with legal requirements and for safety and soundness concerns. This submission reflects changes to certain application procedural requirements in an effort to provide more consistency among publication,

public comment, and meeting procedures for various filings. The remaining requirements are unaffected by this interim rule, but are included in the overall burden estimates discussed below.

Estimated Number of Respondents: 2,108.

Frequency of Response: Event-generated.

Estimated Burden Hours per Response: 17 hours.

Estimated Total Burden: 358 hours.

Mutual Holding Company:

Title of Proposal: Mutual Holding Company.

OMB Number: 1550–0072.

Form Numbers: OTS Forms 1522 (MHC–1) and 1523 (MHC–2).

Regulation requirement: 12 CFR part 575.

Description: These information collections are necessary to fulfill statutory and regulatory requirements and to facilitate review of transactions to prevent insider abuse and unsafe and unsound practices by mutual holding companies and their subsidiaries. This interim final rule revises certain procedural requirements found at § 575.13. The remaining requirements covered by this information collection are unaffected by this interim rule, but are included in the overall burden estimate discussed below.

Affected Public: Savings Associations.

Estimated Number of Respondents: 35.

Estimated Frequency of Response: Event-generated.

Estimated Burden Hours per Response: 350 hours.

Estimated Total Burden: 12,250 hours.

D. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, OTS certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities. The rule makes various changes to OTS application and reporting requirements that reduce regulatory burdens on all savings associations, including small savings associations. These changes should not have a significant impact on small institutions. Accordingly, OTS has determined that regulatory flexibility analysis is not required.

E. Executive Order 12866

The Director of OTS has determined that this interim final rule does not constitute a ''significant regulatory action'' for purposes of Executive Order 12866.

F. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (Unfunded Mandates Act) requires an agency to prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The interim final rule makes various changes that should reduce regulatory burdens on all savings associations. Accordingly, OTS has determined that this rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more and that a budgetary impact statement is not required.

List of Subjects

12 CFR Part 506

Reporting and recordkeeping requirements.

12 CFR Part 516

Administrative practice and procedure, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 528

Advertising, Aged, Civil rights, Credit, Equal employment opportunity, Fair housing, Home mortgage disclosure, Individuals with disabilities, Marital status discrimination, Mortgages, Religious discrimination, Reporting and recordkeeping requirements, Savings associations, Sex discrimination, Signs and symbols.

12 CFR Parts 543 and 544

Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 545

Accounting, Consumer protection, Credit, Electronic funds transfers, Investments, Reporting and recordkeeping requirements, Savings associations.

12 CFR Parts 552 and 563b

Reporting and recordkeeping requirements, Savings associations, Securities.

12 CFR Part 559

Reporting and recordkeeping requirements, Savings associations, Subsidiaries.

12 CFR Part 563

Accounting, Advertising, Crime, Currency, Investments, Reporting and recordkeeping requirements, Savings associations, Securities, Surety bonds.

12 CFR Part 567

Capital, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 574

Administrative practice and procedure, Holding companies, Reporting and recordkeeping requirements, Savings associations, Securities.

12 CFR Part 575

Administrative practice and procedure, Capital, Holding companies, Reporting and recordkeeping requirements, Savings associations, Securities.

Authority and Issuance

■ For the reasons outlined in the preamble, the Office of Thrift Supervision amends chapter V of title 12 of the Code of Federal Regulations, as set forth below:

PART 506—INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT

■ 1. The authority citation for part 506 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

■ 2. Remove the entries for §§ 545.74, 545.92, 545.95, 563.181, and 563.183 in the display chart at § 506.1(b), add a new entry for §§ 545.93 and 545.95 to read as follows:

§ 506.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * * *

(b) *Display.*

12 CFR part or section where identified and described	Current OMB control number
* * * * *	
545.93 and 545.95	1500–0006
* * * * *	

PART 516—APPLICATION PROCESSING PROCEDURES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1462a, 1463, 1464, 2901 *et seq.*

■ 4. Revise § 516.70 to read as follows:

§ 516.70 Where must I publish the public notice?

You must publish the notice in a newspaper having a general circulation in the communities indicated in the following chart:

If you file . . .	You must publish in the following communities . . .
(a) An application for permission to organize under § 543.2 of this chapter, a Bank Merger Act application under 563.22(a) of this chapter, an application to convert to is a federal charter under § 543.8 or § 552.2–6 of this chapter, or an application for a mutual to stock conversion under part 563b of this chapter . . .	The community in which your home office is located.
(b) An application to establish a branch office under § 545.95 of this chapter . . .	The community to be served by the branch office.
(c) An application for the change of permanent location of a home or branch office under § 545.95 of this chapter . . .	The community in which the existing office is located and the community to be served by the new office.
(d) A holding company application or a change of control notice under part 574 of this chapter . . .	The community in which the home office of the savings association whose stock is to be acquired is located and, if applicable, the community in which the home office of the acquiror's largest subsidiary savings association is located.

■ 5. Revise § 516.120(b) to read as follows:

§ 516.120 What information should a comment include?

* * * * *

(b) A commenter must include any request for a meeting under § 516.170 in its comment. The commenter must describe the nature of the issues or facts to be discussed and the reasons why written submissions are insufficient to adequately address these facts or issues.

■ 6. Revise § 516.140 to read as follows:

§ 516.140 How long is the comment period?

(a) *General.* Except as provided in paragraph (b) of this section, a commenter must file a written comment with OTS within 30 calendar days after the date of publication of the initial public notice.

(b) *Late-filed comments.* OTS may consider late-filed comments if OTS determines that the comment will assist in the disposition of the application.

■ 7. Remove § 516.150.

■ 8. Revise subpart D of part 516 to read as follows:

Subpart D—Meeting Procedures

§ 516.160 What does this subpart do?

This subpart contains meeting procedures. It applies whenever a regulation incorporates the procedures in this subpart, or when otherwise required by OTS.

§ 516.170 When will OTS conduct a meeting on an application?

(a) OTS will grant a meeting request or conduct a meeting on its own initiative, if it finds that written submissions are insufficient to address facts or issues raised in an application, or otherwise determines that a meeting will benefit the decision-making process. OTS may limit the issues considered at the meeting to issues that OTS decides are relevant or material.

(b) OTS will inform the applicant and all commenters requesting a meeting of its decision to grant or deny a meeting request, or of its decision to conduct a meeting on its own initiative.

(c) If OTS decides to conduct a meeting, OTS will invite the applicant and any commenters requesting a meeting and raising an issue that OTS intends to consider at the meeting. OTS may also invite other interested persons to attend. OTS will inform the participants of the date, time, location, issues to be considered, and format for the meeting a reasonable time before the meeting.

§ 516.180 What procedures govern the conduct of the meeting?

(a) OTS may conduct meetings in any format including, but not limited to, a telephone conference, a face-to-face meeting, or a more formal meeting.

(b) The Administrative Procedure Act (5 U.S.C. 551 *et seq.*), the Federal Rules of Evidence (28 U.S.C. Appendix), the Federal Rules of Civil Procedure (28 U.S.C. Rule 1 *et seq.*) and the OTS Rules of Practice and Procedure in Adjudicatory Proceedings (12 CFR part 509) do not apply to meetings under this section.

§ 516.185 Will OTS approve or disapprove an application at a meeting?

OTS will not approve or deny an application at a meeting under this subpart.

§ 516.190 Will a meeting affect application processing time frames?

If OTS decides to conduct a meeting, it may suspend applicable application processing time frames, including the time frames for deeming an application complete and the applicable approval time frames in subpart E of this part. If OTS suspends applicable application processing time frames, the time period will resume when OTS determines that a record has been developed that sufficiently supports a determination on the issues considered at the meeting.

PART 528—NONDISCRIMINATION REQUIREMENTS

■ 9. The authority citation for part 528 continues to read as follows:

Authority: 12 U.S.C. 1464, 2810 *et seq.*, 2901 *et seq.*, 15 U.S.C. 1691; 42 U.S.C. 1981, 1982, 3601–3619.

■ 10. Revise the introductory text to § 528.4 to read as follows:

§ 528.4 Nondiscriminatory advertising.

No savings association may directly or indirectly engage in any form of advertising that implies or suggests a policy of discrimination or exclusion in violation of title VIII of the Civil Rights Acts of 1968, the Equal Credit Opportunity Act, or this part 528. Advertisements for any loan for the purpose of purchasing, constructing, improving, repairing, or maintaining a dwelling or any loan secured by a dwelling shall include a facsimile of the following logotype and legend:

* * * * *

PART 543—FEDERAL MUTUAL SAVINGS ASSOCIATIONS—INCORPORATION, ORGANIZATION, AND CONVERSION

■ 11. The authority citation for part 543 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 2901 *et seq.*

■ 12. Revise § 543.2(f) to read as follows:

§ 543.2 Application for permission to organize.

* * * * *

(f) *Meetings.* OTS may arrange a meeting in accordance with the procedures in subpart D of part 516 of this chapter.

* * * * *

PART 544—FEDERAL MUTUAL SAVINGS ASSOCIATIONS—CHARTER AND BY LAWS

■ 13. The authority citation for part 544 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 2901 *et seq.*

■ 14. Revise § 544.2(b)(3) to read as follows:

§ 544.2 Charter amendments.

* * * * *

(b) * * *

(3) *Home office.* A Federal mutual savings association may amend its charter by substituting a new home office in section 2, if it has complied with applicable requirements of § 545.95 of this chapter.

* * * * *

PART 545—FEDERAL SAVINGS ASSOCIATIONS—OPERATIONS

■ 15. The authority citation for part 545 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1828.

■ 16. Remove § 545.74.

■ 17. Revise § 545.91 to read as follows:

§ 545.91 Home office.

(a) All operations of a Federal savings association (''you'') are subject to direction from the home office.

(b) You must notify the appropriate OTS Regional Office if the permanent address of your home office changes, unless you have submitted an application or notice regarding the change under §§ 545.93 and 545.95 of this chapter.

■ 18. Revise § 545.92 to read as follows:

§ 545.92 Branch offices.

(a) *Definition.* A branch office of a Federal savings association (''you'') is any office other than your home office, agency office, administrative office, data processing office, or an electronic means or facility under part 555 of this chapter.

(b) *Branching.* Subject to the application and notice requirements at §§ 545.93 and 545.95 of this chapter, you may branch in any State or States of the United States and its territories unless the location would violate:

(1) Section 5(r) of the HOLA (12 U.S.C. 1464(r));

(2) Section 10(e)(3) of the HOLA (12 U.S.C. 1467a(e)(3)); or

(3) Section 13(k)(4) of the FDIA (12 U.S.C. 1823(k)(4)).

(c) *Preemption.* This exercise of OTS authority is preemptive of any State law purporting to address the subject of branching by a Federal savings association.

■ 19. Revise § 545.93 to read as follows:

§ 545.93 Application and notice requirements for branch and home offices.

(a) *Application and notice requirements.* A Federal savings association (''you'') must file an application or notice and receive OTS approval or non-objection under § 545.95 before you change the permanent location of, or establish a new, home or branch office, except as provided in this section.

(b) *Exceptions.* You are not required to submit an application or notice and receive OTS approval or non-objection under § 545.95 under the following circumstances:

(1) *Drive-in or pedestrian offices.* You may establish a drive-in or pedestrian office that is located within 500 feet of a public entrance to your existing home or branch office, provided the functions performed at the office are limited to functions that are ordinarily performed at a teller window.

(2) *Short-distance relocation.* You may change the permanent location of an existing home or branch office to a site that is within the market area and short-distance location area of the existing home or branch office. The short-distance relocation area of an existing office is the area that is within:

(i) A 1000-foot radius of an existing office that is within a Principal City in a Metropolitan Statistical Area (MSA) designated by the U.S. Department of Commerce;

(ii) A one-mile radius of an existing office that is within an MSA, but is not within a Principal City; or

(iii) A two-mile radius of an existing office that is not in an MSA.

(3) *Highly-rated Federal savings associations.* You may change the permanent location of, or establish a new, branch or home office if you meet all of the following requirements:

(i) You are eligible for expedited treatment under § 516.5 of this chapter. For the purposes of that section, you must meet the capital requirements under part 567 of this chapter before and immediately after you change the location of your home or branch office or establish a new branch office.

(ii) You published a notice of your intent to change the location of your home or branch office or establish a new branch office. To satisfy this publication requirement, you must follow the procedures in subpart B of part 516 of this chapter except that:

(A) Under § 516.55(d) and (e) of this chapter, your public notice must state that the public may submit comments to you and to the appropriate OTS office(s), and must provide addresses for you and for the appropriate OTS office(s) where the public may submit comments;

(B) Section 516.55(g) of this chapter, which addresses public inspections of filings with OTS, does not apply; and

(C) Under § 516.60 of this chapter, you must publish the public notice at least 35 days before you take the proposed action. If you publish a public notice more than 12 months before you take the proposed action, the publication is invalid.

(iii)(A) No person files a comment opposing the proposed action within 30 days after the date of the publication of the proposed notice, or (B) A person files a comment opposing the proposed action and OTS determines that the comment raises issues that are not relevant to the approval standards in § 545.95(b) of this chapter or that OTS action in response to the comment is not required.

(4) *Re-designations of home and branch offices.* You may re-designate an existing branch office as a home office at the same time that you re-designate your existing home office as a branch office.

(c) *Section 5(m) of the HOLA.* If you are incorporated under the laws of, organized in, or do business in the District of Columbia and you satisfy the requirements of paragraph (b) of this section, the Director of OTS has approved your home or branch office changes under section 5(m) of the HOLA.

(d) *Maintenance of branch and home office following conversion, consolidation, purchase of bulk assets, merger, or purchase from receiver.* An existing savings association that converts to a federal savings association may maintain an existing office and a federal savings association may maintain any office acquired through consolidation, purchase of bulk assets, merger or purchase from the receiver of an association, except to the extent that the approval of the conversion, consolidation, merger, or purchase specifies otherwise.

(e) *Prohibition.* You may not file an application or notice (or utilize any exception described in paragraph (b) of

this section) to establish a branch office, if you filed an application to merge or otherwise surrender your charter and the application has been pending for less than six months.

■ 20. Revise § 545.95 to read as follows:

§ 545.95 What processing procedures apply to my home or branch office application and notices?

(a) *Processing procedures.* Applications and notices under § 545.93 are subject to expedited or standard treatment under the application processing procedures at part 516 of this chapter.

(1) *Publication and posting requirements.* (i) You must publish a public notice of your application or notice in accordance with the procedures in subpart B of part 516 of this chapter. Promptly after publication, you must transmit copies of the public notice and the publisher's affidavit to OTS.

(ii) If you propose to change the location of an existing office, you must also post a notice of the application in a prominent location in the office to be relocated. You must post the notice for 30 days from the date of publication of the initial public notice.

(2) *Comment procedures.* Commenters may submit comments on your application or notice in accordance with the procedures in subpart C of part 516 of this chapter.

(3) *Meeting procedures.* OTS may arrange a meeting in accordance with the procedures in subpart D of part 516 of this chapter.

(4) *OTS Review.* OTS will process your application or notice in accordance with the procedures in subpart E of part 516 of this chapter. The applicable review period for applications filed under standard treatment is 30 days rather than the time period specified at § 516.270(a) of this chapter.

(b) *Approval standards.* (1) OTS will approve an application (or not object to a notice), if your overall policies, condition, and operations afford no basis for supervisory objection.

(i) You should meet or exceed minimum capital requirements under part 567 of this chapter and should be at least adequately capitalized as described in § 565.4(b)(2) of this chapter, before and immediately after the proposed action. If you are undercapitalized as described in § 565.4(b)(3), OTS will deny your application (or disapprove your notice), unless the proposed action is otherwise permitted under section 38(e)(4) of the FDIA.

(ii) OTS will evaluate your record of helping to meet the credit needs of your entire community, including low- and moderate-income neighborhoods, under part 563e of this chapter. OTS may:

(A) Deny your application or disapprove your notice based upon this evaluation; or

(B) Impose a condition to the approval of your application (or non-objection to your notice) requiring you to improve specific practices and/or aspects of your performance under part 563e of this chapter. In most cases, a commitment to improve will not be sufficient to overcome a seriously deficient record.

(2) In reviewing your application and notice, OTS may consider information available from any source, including any comments submitted by interested parties or views expressed by interested parties at meetings with OTS.

(3) OTS may approve an amendment to your charter in connection with a home office relocation under this section.

(c) *Expiration of OTS approval.*

(1) You must open or relocate your office within twelve months of OTS approval of your application (or the date of OTS non-objection to your notice), unless OTS prescribes another time period. OTS may extend the time period if it determines that you are making a good-faith effort to promptly open or relocate the proposed office.

(2) If you do not open or relocate the proposed office within this time period, you must comply with the application and notice requirements of this section before you may open or relocate the proposed office.

■ 21. Revise § 545.96 to read as follows:

§ 545.96 Agency office

(a) *General.* A Federal savings association may establish or maintain an agency office to engage in one or more of the following activities: (1) Servicing, originating, or approving loans and contracts; (2) managing or selling real estate owned by the Federal savings association; and (3) conducting fiduciary activities or activities ancillary to the association's fiduciary business in compliance with subpart A of part 550 of this chapter.

(b) *Additional services.* A Federal savings association may request, and OTS may approve, any service not listed in paragraph (a) of this section, except for payment on savings accounts.

(c) *Records.* A Federal savings association must maintain records of all business it transacts at an agency office. It must maintain these records at the agency office, and must transmit copies to a home or branch office.

PART 552—FEDERAL STOCK ASSOCIATIONS—INCORPORATION, ORGANIZATION, AND CONVERSION

■ 22. The authority citation for part 552 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a.

■ 23. Revise § 552.2–1(a)(4) to read as follows:

§ 552.2–1 Procedure for organization of Federal stock association.

(a) * * *

(4) *Meetings.* OTS may arrange a meeting in accordance with the procedures in subpart D of part 516 of this chapter.

* * * * *

■ 24. Revise 552.4(b)(2) to read as follows:

§ 552.4 Charter amendments.

* * * * *

(b) * * *

(2) *Home office.* A Federal savings association may amend its charter by substituting a new home office in section 2, if it has complied with applicable requirements of § 545.95 of this chapter.

* * * * *

PART 559—SUBORDINATE ORGANIZATIONS

■ 25. The authority citation for part 559 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1828.

■ 26. Revise § 559.4(f) to read as follows:

§ 559.4 What activities are preapproved for service corporations?

* * * * *

(f) Securities activities, liquidity management, and coins.

(1) Execution of transactions in securities on an agency or riskless principal basis solely upon the order and for the account of customers or the provision of investment advice. The service corporation must register with the Securities and Exchange Commission and State securities regulators, as required by applicable Federal and State law and regulations.

(2) Liquidity management;

(3) Issuing notes, bonds, debentures, or other obligations or securities;

(4) Purchase or sale of coins issued by the U.S. Treasury.

* * * * *

■ 27. Revise § 559.12 by removing paragraph (d).

PART 563—SAVINGS ASSOCIATIONS—OPERATIONS

■ 28. The authority citation for part 563 continues to read as follows:

Authority: 12 U.S.C. 375b, 1462, 1462a, 1463, 1464, 1467a, 1468, 1817, 1820, 1828, 1831o, 3806; 31 U.S.C. 5318; 42 U.S.C. 4106.

■ 29. Revise § 563.22(e) to read as follows:

§ 563.22 Merger, consolidation, purchase or sale of assets, or assumption of liabilities.

* * * * *

(e)(1) The following procedures apply to applications described in paragraph (a) of this section, unless OTS finds that it must act immediately to prevent the probable default of one of the depository institutions involved:

(i) The applicant must publish a public notice of the application in accordance with the procedures in subpart B of part 516 of this chapter. In addition to the initial publication, the applicant must also publish on a weekly basis during the public comment period.

(ii) Commenters may submit comments on an application in accordance with the procedures in subpart C of part 516 of this chapter. The public comment period is 30 calendar days after the date of publication of the initial public notice. However, if OTS has advised the Attorney General that an emergency exists requiring expeditious action, the public comment period is 10 calendar days after the date of publication of the initial public notice.

(iii) OTS may arrange a meeting in accordance with the procedures in subpart D of part 516 of this chapter.

(iv) OTS will request the Attorney General, the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, and the Federal Deposit Insurance Corporation to provide reports on the competitive impacts involved in the transaction.

(v) OTS will immediately notify the Attorney General of the approval of the transaction. The applicant may not consummate the transaction before the date established under 12 U.S.C. 1828(c)(6).

(2) For applications described in § 563.22, certain savings associations described below must provide affected accountholders with a notice of a proposed account transfer and an option of retaining the account in the transferring savings association. The notice must allow affected accountholders at least 30 days to consider whether to retain their accounts in the transferring savings association. The following savings associations must provide the notices:

(i) A savings association transferring account liabilities to an institution the accounts of which are not insured by the Savings Association Insurance Fund, the Bank Insurance Fund, or the National Credit Union Share Insurance Fund; and

(ii) Any mutual savings association transferring account liabilities to a stock form depository institution.

* * * * *

■ 30. Delete § 563.181.

■ 31. Delete § 563.183

PART 563b—CONVERSIONS FROM MUTUAL TO STOCK FORM

■ 32. The authority citation for part 563b continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 2901; 15 U.S.C. 78c, 78l, 78m, 78n, 78w.

■ 33. Revise § 563b.180 to read as follows:

§ 563b.180 How do I notify the public that I filed an application for conversion?

(a) You must publish a public notice of the application in accordance with the procedures in subpart B of part 516 of this chapter. You must simultaneously prominently post the notice in your home office and all branch offices.

(b) Promptly after publication, you must file four copies of any public notice and an affidavit of publication from each publisher. You must file the original and one copy with the Applications Filing Room in Washington, and two copies with the appropriate Regional Office at the addresses in § 516.40 of this chapter.

(c) If OTS does not accept your application for conversion under § 563b.200 and requires you to file a new application, you must publish and post a new notice and allow an additional 30 days for comment.

■ 34. Revise § 563b.185 to read as follows:

§ 563b.185 How may a person comment on my application for conversion?

Commenters may submit comments on your application in accordance with the procedures in subpart C of part 516 of this chapter. A commenter must file the original and one copy of any comments with the Applications Filing Room in Washington and two copies with the appropriate Regional Office at the addresses in § 516.40 of this chapter.

PART 567—CAPITAL

■ 35. The authority citation for part 567 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 1828 (note).

■ 36. Remove § 567.13.

PART 574—ACQUISITION OF CONTROL OF SAVINGS ASSOCIATIONS

■ 37. The authority citation for part 574 continues to read as follows:

Authority: 12 U.S.C. 1467a, 1817, 1831i.

■ 38. Revise § 574.6(c)(2)(iii), (d) and (e) to read as follows:

§ 574.6 Procedural requirements.

* * * * *

(c) * * *

(2) * * *

(iii) Is materially deficient and will not be processed. The Office shall also notify an acquiror in writing within 15 calendar days after proper filing of any additional information furnished in response to a specific request by the Office as to whether the application or notice is thereby deemed to be sufficient. If the Office fails to so notify an acquiror within such time, the application or notice shall be deemed to be sufficient as of the expiration of the applicable period.

* * * * *

(d) *Public notice.* (1) The acquiror must publish a public notice of an application under § 574.3(a) or § 574.8 of this chapter or a notice under § 574.3(b) of this chapter, in accordance with the procedures in subpart B of part 516 of this chapter. Promptly after publication, the acquiror must transmit copies of the public notice and the publisher's affidavit to OTS.

(2) The acquiror must provide a copy of the public notice to the savings association whose stock is sought to be acquired, and may provide a copy of the public notice to any other person who may have an interest in the application.

(3) OTS will notify the appropriate state supervisor and will notify persons whose requests for announcements, as described in 12 CFR part 563e, Appendix B, have been received in time for the notification. OTS may also notify any other persons who may have an interest in the application or notice.

(e) *Submission of comments.* Commenters may submit comments on the application or notice in accordance with the procedures in subpart C of part 516 of this chapter.

* * * * *

PART 575—MUTUAL HOLDING COMPANIES

■ 39. The authority citation for part 575 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 1828, 2901.

■ 40. In § 575.13, revise paragraphs (c)(3) and (f), and delete paragraphs (c)(4) and (g) to read as follows:

§ 575.13 Procedural requirements.

* * * * *

(c) * * *

(3) *Public notice, public comment, and meetings.* This part imposes no requirements regarding public notice, public comment, or meetings for mutual holding company reorganizations. However, mutual holding company reorganizations under this part are subject to applicable public notice, public comment, and meeting requirements under the Bank Merger Act regulations at § 563.22(e)(1) of this chapter and the Savings and Loan Holding Company Act regulations at § 574.6(d) and (e) of this chapter.

* * * * *

(f) *Disclosure.* The rules governing disclosure of any notice or application submitted pursuant to this part, or any public comment submitted pursuant to paragraph (c) of this section, shall be the same as set forth in § 574.6(f) of this chapter for notices, applications, and public comments filed under part 574 of this chapter.

* * * * *

Dated: November 18, 2004.

By the Office of Thrift Supervision.

James E. Gilleran,

Director.

[FR Doc. 04–26010 Filed 11–23–04; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NE–51–AD; Amendment 39–13881; AD 2004–24–05]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd. & Co KG (formerly Rolls-Royce plc), Models Spey 555–15, 555–15H, 555–15N, and 555–15P Turbojet Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Rolls-Royce Deutschland Ltd. & Co KG (RRD) (formerly Rolls-Royce plc), models Spey 555–15, 555–15H, 555–15N, and 555–15P turbojet engines, with magnesium split low pressure (LP) compressor case, part number (P/N) EU.73418A installed. This AD requires replacement of the magnesium split LP compressor case with a serviceable compressor case that is a combination of a steel front LP compressor case and a shortened split compressor case. This AD results from several reports of bird ingestion and LP compressor stage 1 rotor blade failures that have resulted in penetration of the magnesium LP compressor case, and damage to the airplane.

DATES: This AD becomes effective December 29, 2004.

ADDRESSES: You can get the service information identified in this AD from Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, D–15827 Dahlewitz, Germany, telephone +49 (0) 33–7086–1768; fax +49 (0) 33–7086–3356.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7747; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with a proposed AD. The proposed AD applies to RRD models Spey 555–15, 555–15H, 555–15N, and 555–15P turbojet engines, with magnesium split LP compressor case, P/N EU.73418A installed. We published the proposed AD in the **Federal Register** on February 20, 2003 (68 FR 8157). That action proposed to require replacement of the magnesium split LP compressor case with a serviceable LP compressor case that is a combination of a steel front LP compressor case and a shortened split LP compressor case.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the one comment received.

One commenter requests that special flight permits be added to the final rule. We do not agree. On July 22, 2002, the FAA revised 14 CFR part 39 by adding the Special Flight Permit provision. Doing this allowed us to omit that provision from ADs, to help place the focus of ADs on the unsafe condition that created the need for each directive. ADs that allow Special Flight Permits with conditions, or that prohibit Special Flight Permits, will state those conditions in the compliance section. ADs that do not specify special flight conditions or do not prohibit special flight permits will not reference Special Flight Permits. If operators want to request Special Flight Permits, they must request them by following the procedure in 14 CFR part 39, § 39.25. Also, because this final rule requires that the actions be done within 60 months after the effective date of the AD, we anticipate no requests for a Special Flight Permit due to the amount of lead time available to comply with the AD.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 184 RRD models Spey 555–15, 555–15H, 555–15N, and 555–15P turbojet engines of the affected design in the worldwide fleet. We estimate that 34 engines installed on airplanes of U.S. registry will be affected by this AD. We also estimate that it will take about 6 work hours per engine to perform the actions, and that the average labor rate is $65 per work hour. Required parts will cost about $37,000 per engine. Based on these figures, we estimate the total cost of the AD to U.S. operators to be $1,271,260.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD and placed it in

the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include ''AD Docket No. 2003–NE–51–AD'' in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2004–24–05 Rolls-Royce Deutschland Ltd. & Co KG (formerly Rolls-Royce plc): Amendment 39–13881. Docket No. 2003–NE–51–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective December 29, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Rolls-Royce Deutschland Ltd. & Co KG (RRD) (formerly Rolls-Royce plc), models Spey 555–15, 555–15H, 555–15N, and 555–15P turbojet engines, with magnesium split low pressure (LP) compressor case, part number (P/N) EU.73418A installed. These engines are installed on, but not limited to, Fokker F.28 Mark 1000, Mark 2000, Mark 3000, and Mark 4000 series airplanes.

Unsafe Condition

(d) This AD is prompted by several reports of bird ingestion and LP compressor stage 1 rotor blade failures that have resulted in penetration of the magnesium split LP compressor case and damage to the airplane. We are issuing this AD to prevent possible uncontained LP compressor stage 1 rotor blade failures that could result in damage to the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within 60 months after the effective date of this AD, unless the actions have already been done.

Replacement of Magnesium Split LP Compressor Case With a Serviceable Compressor Case

(f) Remove the magnesium split LP compressor case, P/N EU.73418A, from the engine and install a serviceable LP compressor case. Information on removing and replacing this P/N case can be found in RRD Service Bulletin No. Sp72–893, Revision 3, dated August 25, 2003.

Alternative Methods of Compliance

(g) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(h) None.

Related Information

(i) LBA airworthiness directive 2003–261, dated August 25, 2003, also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on November 15, 2004.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04–25790 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Estradiol Benzoate and Testosterone Propionate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth, and Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental NADAs provide for the addition of statements to labeling of subcutaneous implants containing estradiol benzoate and testosterone propionate warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective November 24, 2004.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 011–427 for SYNOVEX H (estradiol benzoate and testosterone propionate). Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 135–906 for COMPONENT E–H (estradiol benzoate and testosterone propionate) and COMPONENT E–H with TYLAN (estradiol benzoate and testosterone propionate with tylosin tartrate). The supplemental NADAs provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 18, 2004, and the regulations are amended in 21 CFR 522.842 to reflect the approvals and a current format. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.842 is revised to read as follows:

§ 522.842 Estradiol benzoate and testosterone propionate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 000856 for use as in paragraph (c)(1)(i), (c)(2), and (c)(3) of this section.

(2) No. 021641 for use as in paragraph (c) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.710 of this chapter.

(c) *Conditions of use.* For implantation in heifers as follows:

(1) *Amount.* (i) 20 milligrams (mg) estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 8 pellets, each pellet containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate) per implant dose.

(ii) 20 mg estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 9 pellets, each of 8 pellets containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(3) *Limitations.* For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 5, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–25977 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate and Estradiol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Intervet Inc.; three supplemental abbreviated new animal drug applications (ANADAs) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc.; and a supplemental ANADA filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADAs and ANADAs provide for the addition of statements to labeling of subcutaneous implants containing trenbolone acetate and estradiol warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective November 24, 2004.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Intervet Inc., 29160 Intervet Lane, P.O. Box 318, Millsboro, DE 19966, filed supplements to NADA 140–897 and NADA 140–992 for REVALOR (trenbolone acetate and estradiol) implants. Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplements to ANADA 200–221 and ANADA 200–346 for COMPONENT (trenbolone acetate and estradiol) and COMPONENT plus TYLAN (trenbolone acetate and estradiol with tylosin tartrate) implants. Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to ANADA 200–367 for SYNOVEX (trenbolone acetate and estradiol) implants. The supplemental NADAs and ANADAs provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 28, 2004, and the regulations are amended in 21 CFR 522.2477 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.2477 is amended by revising paragraphs (d)(1)(iii), (d)(2)(iii), and (d)(3)(iii) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 10, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–25978 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 2004N–0482]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, the Food and Drug Administration Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002. The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule becomes effective December 27, 2004. The classification was effective August 24, 2004.

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, ext. 144.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a notice on June 9, 2004, classifying the Perkin Elmer Life and Analytical Sciences' NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On July 2, 2004, Perkin Elmer Life and Analytical Sciences submitted a petition requesting classification of the NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Perkin Elmer Life and Analytical Sciences' NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.'' It is identified as a device intended for the measurement and evaluation of amino acids, free carnitine, and acylcarnitine concentrations from newborn whole blood filter paper samples. The quantitative analysis of amino acids, free carnitine, and acylcarnitines and their relationship with each other provides analyte concentration profiles that may aid in screening newborns for one or more inborn errors of amino acid, free carnitine, and acyl-carnitine metabolism.

FDA has identified no direct risks to health related to use of newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry. However, failure of the test to perform as indicated or error in interpretation of results may lead to the indirect risk of improper medical management of patients with inborn errors of metabolism. For example, a false negative (false normal) measurement could contribute to failure to detect a possible inborn error of metabolism, which could lead to functional impairment or death. A false positive (false abnormal) measurement could contribute to unnecessary additional patient testing and added concern and apprehension of parents and physicians.

The class II special controls guidance document provides information on how to meet premarket (510(k)) submission requirements for the device, including recommendations on validation of performance characteristics and labeling. FDA believes that following the class II special controls guidance document generally addresses the risk to health identified in the previous paragraph. Therefore, on August 24, 2004, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding 21 CFR 862.3840.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket notification is necessary because FDA review of performance characteristics, test methodology, and labeling to satisfy requirements of § 807.87(e), will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type of device must submit to FDA a premarket notification containing information on the newborn test system before marketing the device.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Perkin Elmer Life and Analytical Sciences, dated July 2, 2004.

List of Subjects in 21 CFR Part 862

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 862.1055 is added to subpart B to read as follows:

§ 862.1055 Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.

(a) *Identification*. A newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry is a device that consists of stable isotope internal standards, control materials, extraction solutions, flow solvents, instrumentation, software packages, and other reagents and materials. The device is intended for the measurement and evaluation of amino acids, free carnitine, and acylcarnitine concentrations from newborn whole blood filter paper samples. The quantitative analysis of amino acids, free carnitine, and acylcarnitines and their relationship with each other provides analyte concentration profiles that may aid in screening newborns for one or more inborn errors of amino acid, free carnitine, and acyl-carnitine metabolism.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry.'' See § 862.1(d) for the availability of this guidance document.

Dated: November 15, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–25975 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3515, MB Docket No. 04–164, RM–10548, RM–11048]

Radio Broadcasting Services; Quincy, Portola, and Susanville, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document grants a petition filed by Corey J. McCaslin proposing the allotment of Channel 282A at Susanville, California, as its fourth FM broadcast service and substitution of Channel 265A for Channel 262A at Quincy and modification of the Station KHGQ(FM) license accordingly. *See* 69 FR 29917, published March 26, 2004. This document also grants a counterproposal filed by Eastern Sierra Broadcasting by allotting Channel 269A to Portola, California, as its first local service. This document also dismissed a counterproposal filed by Keily Miller, licensee of Station KHGQ(FM) requesting the reallotment of Channel 262A from Quincy to Durham, California, as its first local service. *See* **SUPPLEMENTARY INFORMATION.**

DATES: Effective December 20, 2004.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MB Docket No. 04–164 adopted November 3, 2004, and released November 5, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the General Accounting Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Channel 262A can be allotted to Susanville consistent with the Commission's minimum distance separation requirements at city reference coordinates. The reference coordinates for Channel 262A at Susanville are 40–24–59 North Latitude and 120–39–07 West Longitude. To accommodate the Susanville allotment, Channel 265A can be substituted at Quincy consistent with the Commission's minimum distance separation requirements at the current license site for Station KHGQ(FM). The coordinates for Channel 265A at Quincy are 39–56–15 North Latitude and 120–56–49 West Longitude. Additionally, Channel 269A can be allotted to Portola, in compliance with the Commission's minimum distance separation requirements provided there is a site restriction of 3.0 kilometers (1.8 miles) north of the community. The reference coordinates for Channel 269A at Portola are 39–49–59 North Latitude and 120–28–54 West Longitude.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 262A and adding Channel 265A at Quincy, by adding Portola, Channel 269A, and by adding Channel 262A at Susanville.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 04–26062 Filed 11–23–04; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 69, No. 226
Wednesday, November 24, 2004

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 563e

[No. 2004–53]

RIN 1550–AB48

Community Reinvestment Act—Community Development, Assigned Ratings

AGENCY: Office of Thrift Supervision, Treasury (OTS).

ACTION: Notice of proposed rulemaking.

SUMMARY: In this notice of proposed rulemaking (proposal), OTS is proposing changes to, and soliciting comment on, its Community Reinvestment Act (CRA) regulations in two areas to reduce burden.

First, OTS is proposing to revise the definition of ''community development'' to encourage all savings associations to increase their community development lending, qualified investments, and community development services in rural areas, with a particular focus on increasing these activities in underserved nonmetropolitan areas. The proposal also solicits comment on further encouraging savings associations to perform community development activities in any areas affected by natural or other disasters or other major community disruptions.

Second, the proposal solicits comment on providing additional flexibility in assigning CRA ratings to encourage large retail savings associations to focus their community reinvestment efforts on the types of activities the communities they serve need, consistent with safe and sound operations. As an alternative, the proposal solicits comment on eliminating the investment test.

Today's proposed changes are designed to reduce burden to the extent consistent with safe and sound supervision of the industry. They would further the CRA burden reduction OTS began in its final rule published in the **Federal Register** on August 18, 2004, which revised the definition of ''small savings association.'' They would also further the burden reductions in the interim final rule published elsewhere in today's **Federal Register** as part of OTS's review of regulations under section 2222 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA).

DATES: Comments must be received by January 24, 2005.

ADDRESSES: You may submit comments, identified by No. 2004–53, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- E-mail address: *regs.comments@ots.treas.gov*. Please include No. 2004–53 in the subject line of the message and include your name and telephone number in the message.
- Fax: (202) 906–6518.
- Mail: Regulation Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention: No. 2004–53.
- Hand Delivery/Courier: Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9 a.m. to 4 p.m. on business days, Attention: Regulation Comments, Chief Counsel's Office, Attention: No. 2004–53.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to the OTS Internet site at *http://www.ots.treas.gov/pagehtml.cfm?catNumber=67&an=1*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.ots.treas.gov/pagehtml.cfm?catNumber=67&an=1*.

In addition, you may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment for access, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov*, or send a facsimile transmission to (202) 906–7755. (Prior notice identifying the materials you will be requesting will assist us in serving you.) We schedule appointments on business days between 10 a.m. and 4 p.m. In most cases, appointments will be available the next business day following the date we receive a request.

FOR FURTHER INFORMATION CONTACT: Theresa A. Stark, Program Manager, Thrift Policy, (202) 906–7054; Richard Bennett, Counsel (Banking and Finance), Regulations and Legislation Division, (202) 906–7409, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

Introduction

After considering the comments on a joint advance notice of proposed rulemaking (ANPR) published on July 19, 2001 (66 FR 37602), and a joint notice of proposed rulemaking (NPR) published on February 6, 2004 (69 FR 5729), OTS is proposing changes to, and soliciting comment on, its CRA regulations in two areas: (1) The definition of ''community development'' and (2) the assignment of ratings. These proposed changes are designed to reduce burden to the extent consistent with the safe and sound supervision of the industry. These changes would provide institutions with more flexibility to make their own determinations about how best to serve their communities. They would further the CRA burden reduction OTS began in its final rule published in the **Federal Register** on August 18, 2004, which revised the definition of ''small savings association.'' 69 FR 51155. They would also complement the burden reductions contained in OTS's interim final rule published elsewhere in today's **Federal Register** as part of OTS's review of regulations under section 2222 of the EGRPRA (Pub. L. 104–208, Sept. 30, 1996). The related EGRPRA rule is reducing regulatory burden on savings associations by updating and revising various application and reporting requirements.

Community Development Proposal

OTS is proposing to revise the definition of ''community development.'' The proposal is designed to encourage all savings associations to increase their community development lending, qualified investments, and community development services in rural areas, with a particular focus on increasing these activities in underserved nonmetropolitan areas. The proposal also solicits comment on

further encouraging savings associations to perform community development activities in any areas affected by natural or other disasters or other major community disruptions. OTS is considering these revisions to encourage more community development activities in rural areas, to cover the full range of activities that should receive favorable consideration in all areas, and to reduce burden by affording savings associations greater flexibility in serving their communities.

The Current Rule

Under the current definition in section 563e.12(f) of OTS's regulation, ''community development'' means:

(1) Affordable housing (including multifamily rental housing) for low-or moderate-income individuals;

(2) Community services targeted to low-or moderate-income individuals;

(3) Activities that promote economic development by financing businesses or farms that meet the size eligibility standards of the Small Business Administration's Development Company or Small Business Investment Company programs (13 CFR 121.301) or have gross annual revenues of $1 million or less; or

(4) Activities that revitalize or stabilize low-or moderate-income geographies. *See* 69 FR 41181, 41188 (July 8, 2004) (redesignating the definition of ''community development'' as paragraph (f) of section 563e.12, among other changes).

The 2001 ANPR

As discussed in the 2001 ANPR, ''[S]ome [commenters] indicate that many projects intended to revitalize or stabilize rural communities do not qualify under the current regulatory definition of community development because they are not located in low- or moderate-income geographies as defined in the regulations. Others assert that the definition does not adequately value activities benefiting communities or projects involving persons with a mix of incomes.'' 66 FR at 37605.

As explained in the preamble to the 2004 NPR, commenters on the 2001 ANPR were split over the appropriateness of the current definition of ''community development.'' Financial institutions asked the banking agencies to remove from the definition of ''community development'' the requirement that community development activities target primarily low- or moderate-income individuals or areas, and expand the definition to include community-building activities that incidentally benefit low- or moderate-income individuals or areas. For instance, several financial institutions contended that any activity that helps ''revitalize and stabilize'' an area (*e.g.*, after a natural disaster or a steady economic decline) should be considered community development, even if the activity is not located in, or targeted to, low- or moderate-income communities. Other examples of activities for which they sought consideration included municipal bonds and grants to cultural organizations and other charities. In contrast, community organizations that expressed a view favored retaining the current definition of ''community development'' or narrowing it. For example, many community organizations sought to limit the ''economic development'' component of the definition to financing minority-owned businesses or farms and businesses or farms in low- or moderate-income areas. 69 FR at 5733.

The 2004 NPR

The 2004 NPR did not propose to revise the definition of ''community development.'' Thus, it did not specifically solicit comment on this issue and commenters did not focus on it. But as noted in the preamble to OTS's August 18th final rule, community organizations opposed to changing the definition of ''small institution'' were primarily concerned that reducing the number of institutions subject to the large retail institution test—and therefore, the investment test—would reduce the level of investment in low- and moderate-income urban and rural communities. 69 FR at 51157. Further, some in Congress submitted comments encouraging the banking agencies to expand the definition of ''community development.'' A few other commenters supported giving more weight to philanthropy in underserved markets.

Today's Proposal

Today's proposal on the definition of ''community development'' would address rural areas as well as any areas affected by natural or other disasters or other major community disruptions.

With respect to rural areas, the second and fourth paragraphs of the community development definition would be expanded. Thus, under the proposed expanded definition, community development would also include: (1) Community services targeted to individuals in rural areas; and (2) activities that revitalize or stabilize rural areas. Community development activities in rural areas would be covered even if the individuals or areas served are not low- or moderate-income. This would contrast with the current definition of ''community development,'' which focuses on activities that benefit low- and moderate-income individuals or geographies.

OTS is proposing this change to reduce burden and provide greater flexibility. OTS is responding to concerns that competition for scarce CRA loans and investments in certain metropolitan areas not only disadvantages small institutions that cannot compete for quality CRA loans and investments, but also results in a largely urban CRA focus. OTS's examination experience indicates that rural areas tend to be composed of mixed-income census tracts that may not qualify as low- or moderate-income areas. Expanding the definition of ''community development'' as proposed would further encourage savings associations to engage in community development activities outside of their traditional CRA market—while still applying existing standards for consideration of activities inside or outside the assessment area(s)—and thereby encourage the extension of CRA and community development to currently underserved and overlooked rural communities.

As explained in OTS's August 18th final rule, even with respect to small savings associations, OTS already considers performance in making community development loans and qualified investments and providing community development services, at the savings association's request, for purposes of raising a rating. 69 FR at 51159. Thus, the proposed change to the definition of ''community development'' is designed to encourage all thrifts—large and small—to increase their community development activities in rural areas, with a particular focus on increasing these activities in underserved nonmetropolitan areas.

OTS is not proposing a specific definition of ''rural'' at this time. However, it solicits comments on the appropriate definition below.

The proposal also solicits comment below on further encouraging savings associations to perform community development activities in any areas affected by natural or other disasters or other major community disruptions. This portion of the proposal would not be limited to rural areas or activities targeted to low- or moderate-income individuals or low- or moderate-income geographies. OTS has not, however, included proposed rule text that would address this possible change.

Solicitation of Comment on Community Development Proposal

OTS solicits comments on all aspects of this proposal.

A. Solicitation of Comments on the Definition of ''Community Development''

1. Should the definition of ''community development'' be expanded? If so, how?

2. Does the proposed change to the community development definition encompass the full range of community development activity that benefits rural areas? Should the definition include a savings association's demonstrated participation in other types of community activities? Should the regulation provide for the Director of OTS to determine that additional activities that benefit the public welfare constitute ''community development?''

3. OTS has indicated in the wake of natural disasters and the September 11th terrorist attacks, that it would take into account an institution's response to its community when evaluating the institution's stabilization activities under CRA. Would it be appropriate for the definition of ''community development'' to expressly provide that community development also includes, in any area (rural or not, low- or moderate-income or not): (1) Community services targeted to individuals in areas affected by natural or other disasters or other major community disruptions; and (2) activities that revitalize or stabilize areas affected by natural or other disasters or other major community disruptions? What other types of major community disruptions should be covered (*e.g.*, civil unrest, arson)?

4. As proposed, OTS would not expand the first paragraph of the definition of ''community development'' to include affordable housing (including multifamily rental housing) for individuals in rural areas who are not low- or moderate-income. Would it be appropriate to cover such activities? Do such activities contribute to community development? If so, how? Are there difficulties with housing affordability and availability in rural areas (*e.g.*, marketability on the secondary mortgage market) that could appropriately be addressed by revising the definition of ''community development?''

5. As proposed, OTS would not expand the third paragraph of the definition of ''community development'' to include activities that promote economic development by financing businesses or farms in rural areas without regard to their size or gross annual revenues. Would it be appropriate to cover such activities? Do such activities contribute to community development? If so, how? Are there difficulties with financing business or farms of various sizes or gross annual revenues in rural areas that could appropriately be addressed by revising the definition of ''community development?''

6. What would be the impact of the proposed definitional change for purposes of the community development test for wholesale or limited purpose savings associations, the large retail institution test, the small savings association test, and any other provisions of the CRA regulation affected?

B. Solicitation of Comment on the Definition of ''Rural''

1. Would a definition of ''rural'' be helpful? If so, how should ''rural'' be defined?

2. Would the definition of ''nonmetropolitan area,'' which is to be incorporated in section 563e.12(r) of OTS's CRA regulation, be appropriate (*i.e.*, any area that is not located in a metropolitan statistical area)? *See* 69 FR at 41188. This definition is derived from the Office of Management and Budget's Standards for Defining Metropolitan and Micropolitan Statistical Areas. 65 FR 82228 (December 27, 2000). However, OMB has indicated, ''The Metropolitan and Micropolitan Statistical Area Standards do not equate to an urban-rural classification; many counties included in Metropolitan and Micropolitan Statistical Areas, and many other counties, contain both urban and rural territory and populations.'' OMB Bulletin No. 04–03 (February 18, 2004), available at, *http://www.whitehouse.gov/omb/bulletins/fy04/b04–03.html.*

3. Are there other definitions that would be appropriate? For example:

a. The U.S. Census Bureau classifies as ''urban'' all territory, population, and housing units located within an urbanized area (UA) or an urban cluster (UC). It delineates UA and UC boundaries to encompass densely settled territory, which consists of:

(1) Core census block groups or blocks that have a population density of at least 1,000 people per square mile and (2) surrounding census blocks that have an overall density of at least 500 people per square mile. In addition, under certain conditions, less densely settled territory may be part of each UA or UC. The Census Bureau's classification of ''rural'' consists of all territory, population, and housing units located outside of UAs and UCs. The rural component contains both place and nonplace territory. Geographic entities, such as census tracts, counties, metropolitan areas, and the territory outside metropolitan areas, often are ''split'' between urban and rural territory, and the population and housing units they contain often are partly classified as urban and partly classified as rural. *See* ''Census 2000 Urban and Rural Classification,'' available at *http://www.census.gov/geo/www/ua/ua_2k.html.*

b. The U.S. Department of Agriculture (USDA) uses various definitions.

i. One definition groups counties according to their official status as metropolitan or nonmetropolitan under OMB standards. It then applies 9 rural-urban continuum codes to further distinguish among metropolitan counties by size and nonmetropolitan counties by their degree of urbanization or proximity to metropolitan areas. Codes 1 through 3 are various types of metropolitan counties while codes 4 through 9 are various types of nonmetropolitan. Within nonmetropolitan areas, Code 8 is a county that is completely rural or has less than 2,500 in urban population and is adjacent to a metropolitan area, while Code 9 is a county that is completely rural or has less than 2,500 in urban population and is not adjacent to a metropolitan area. *See* ''What is Rural?'' available at *http://www.nal.usda.gov/ric/faqs/ruralfaq.htm* and ''Measuring Rurality: Rural-Urban Continuum Codes,'' available at *http://www.ers.usda.gov/briefing/rurality/RuralUrbCon*.

ii. Another definition, contained in the Farm Security and Rural Investment Act of 2002, applies generally to the USDA's Rural Community Advancement programs. It defines ''rural'' and ''rural area'' generally to mean ''any area other than a city or town that has a population of greater than 50,000 inhabitants; and the urbanized area contiguous and adjacent to such a city or town.'' 7 U.S.C. 1991(a)(13).

iii. Another definition, applicable to the Rural Empowerment Zones and Enterprise Communities initiative, generally defines a ''rural area'' as consisting of any area that lies outside the boundaries of a Metropolitan Area, as designated by OMB, or an area that has a population density less than or equal to 1,000 persons per square mile, the land use of which is primarily agricultural. 7 CFR 25.503(a).

Assigned Ratings Proposal

OTS is soliciting comment on providing additional flexibility in the way that CRA ratings are assigned. This

change would reduce burden and encourage large retail savings associations to focus their community reinvestment efforts on the types of activities the communities they serve need, consistent with safe and sound operations. As an alternative way to reduce burden, the proposal solicits comment on eliminating the investment test.

The Current Rule

Under the CRA regulation at 12 CFR 563e.28(b), OTS assigns ratings to savings associations assessed under the lending, investment, and service tests in accordance with the following three rating principles:

(1) A savings association that receives an ''outstanding'' rating on the lending test receives an assigned rating of at least ''satisfactory'';

(2) A savings association that receives an ''outstanding'' rating on both the service test and the investment test and a rating of at least ''high satisfactory'' on the lending test receives an assigned rating of ''outstanding''; and

(3) No savings association may receive an assigned rating of ''satisfactory'' or higher unless it receives a rating of at least ''low satisfactory'' on the lending test.

The Interagency Questions and Answers Regarding Community Reinvestment, 66 FR 36620 (July 12, 2001), address how the banking agencies weight performance under the lending, investment, and service tests for large retail institutions. Q&A 28(a)–3, 66 FR at 36639, provides:

A rating of ''outstanding,'' ''high satisfactory,'' ''low satisfactory,'' ''needs to improve,'' or ''substantial noncompliance,'' based on a judgment supported by facts and data, will be assigned under each performance test. Points will then be assigned to each rating as described in the first matrix set forth below. A large retail institution's overall rating under the lending, investment and service tests will then be calculated in accordance with the second matrix set forth below, which incorporates the rating principles in the regulation.

The Q&A then sets forth the following matrices (66 FR at 36639–36640):

POINTS ASSIGNED FOR PERFORMANCE UNDER LENDING, INVESTMENT AND SERVICE TESTS

	Lending	Service	Investment
Outstanding	12	6	6
High Satisfactory	9	4	4
Low Satisfactory	6	3	3
Needs to Improve	3	1	1
Substantial Noncompliance	0	0	0

COMPOSITE RATING POINT REQUIREMENTS

[Add points from three tests]

Rating	Total points
Outstanding	20 or over.
Satisfactory	11 through 19.
Needs to Improve	5 through 10.
Substantial Noncompliance	0 through 4.

Note: There is one exception to the Composite Rating matrix. An institution may not receive a rating of ''satisfactory'' unless it receives at least ''low satisfactory'' on the lending test. Therefore, the total points are capped at three times the lending test score.

As reflected in the first matrix, currently approximately 50 percent weight is given to lending, and approximately 25 percent weight is given to services and investments each.

Under section 563e.21(b) of OTS's CRA regulation, OTS applies the tests in a performance context that considers the following:

(1) Demographic data on median income levels, distribution of household income, nature of housing stock, housing costs, and other relevant data pertaining to a savings association's assessment area(s);

(2) Any information about lending, investment, and service opportunities in the savings association's assessment area(s) maintained by the savings association or obtained from community organizations, state, local, and tribal governments, economic development agencies, or other sources;

(3) The savings association's product offerings and business strategy as determined from data provided by the savings association;

(4) Institutional capacity and constraints, including the size and financial condition of the savings association, the economic climate (national, regional, and local), safety and soundness limitations, and any other factors that significantly affect the savings association's ability to provide lending, investments, or services in its assessment area(s);

(5) The savings association's past performance and the performance of similarly situated lenders;

(6) The savings association's public file, as described in section 563e.43, and any written comments about the savings association's CRA performance submitted to the savings association or the OTS; and

(7) Any other information deemed relevant by the OTS.

The CRA regulation has been implemented to consider factors outside of a savings association's control that prevent it from engaging in certain activities. When the banking agencies promulgated the 1995 CRA rule, they specifically noted in the preamble:

Statutory limits on investment authority. Several thrift commenters had concerns about the application of the investment test to thrift institutions because of their limited investment authority. Rather than providing a blanket exemption from the investment test, the final rule modifies the ''capacity and constraints'' section of the performance context to clarify that examiners should consider an institution's investment authority in evaluating performance under the investment test. *A thrift that has few or no qualified investments may still be considered to be performing adequately under the investment test if, for example, the institution is particularly effective in responding to the community's credit needs through community development lending activities.*

60 FR 22156, 22163 (May 4, 1995) (emphasis added).

This flexible approach for evaluating the performance of savings associations was restated in the interagency CRA Qs&As. These Qs&As specifically acknowledge that limitations on institutional capacity and constraints will be considered in evaluating performance under the investment test. Q&A 21(b)(4)–1 asks, ''Will examiners consider factors outside of an institution's control that prevent it from engaging in certain activities?'' 66 FR at 36631. The answer provided states:

Yes. Examiners will take into account statutory and supervisory limitations on an institution's ability to engage in any lending, investment, and service activities. *For example, a savings association that has made few or no qualified investments due to its limited*

investment authority may still receive a low satisfactory rating under the investment test if it has a strong lending record.

66 FR at 36631 (emphasis added).

The CRA regulation also emphasizes that the rating assigned reflects the savings association's record of helping to meet the credit needs of its entire community, including low- and moderate-income neighborhoods, ''consistent with the safe and sound operation of the savings association.'' 12 CFR 563e.21(c). The CRA regulation goes on to elaborate in 12 CFR 563e.21(d):

Safe and sound operations. This part and the CRA do not require a savings association to make loans or investments or to provide services that are inconsistent with safe and sound operations. To the contrary, the OTS anticipates savings associations can meet the standards of this part with safe and sound loans, investments, and services on which the savings associations expect to make a profit. Savings associations are permitted and encouraged to develop and apply flexible underwriting standards for loans that benefit low- or moderate-income geographies or individuals, only if consistent with safe and sound operations.

The 2001 ANPR

The 2001 ANPR contained extensive discussion of the way performance of large retail institutions is assessed under the lending, investment, and service tests. It explained that the regulations attempt to temper their reliance on quantitative factors by requiring examiners to evaluate qualitative factors, because not all activities of the same numerical magnitude have equal impact or entail the same relative importance when undertaken by different institutions in different communities. It also indicated that institutions' CRA ratings reflect the principle that lending is the primary vehicle for meeting a community's credit needs. It noted that in the preamble to the 1995 CRA rule, the banking agencies published a ratings matrix for examiners to use when evaluating large retail institutions under the lending, investment, and service tests. Under this matrix, it is impossible for an institution to achieve a ''satisfactory'' rating overall unless it receives at least a ''low satisfactory'' rating on the lending test. 66 FR at 37604.

In publishing the matrix in 1995, the banking agencies noted that they were not incorporating it into the CRA rule itself, to allow some flexibility to adjust the matrix to prevent unintended anomalies that may be found during the examination process. The preamble noted that if the banking agencies were to change the matrix in the future, the new matrix would be published for information, but not necessarily for comment, in the **Federal Register**. 60 FR at 22170. As discussed above, the matrix is currently published in Q&A 28(a)–3.

With respect to the emphasis placed on each category of an institution's activities under the large retail institution test, the 2001 ANPR indicated that some contended that lending should always be stressed, because they believe that deposits derived from communities should be reinvested in those communities through loans. Still others asserted that lending should be the only basis upon which institutions are evaluated. 66 FR at 37604.

In contrast, some questioned whether lending should be emphasized more than investments and services. Some asserted that a CRA evaluation should allow for adjustment of this emphasis in a manner that more nearly corresponds with the activities of the institution and the particular needs of its community. For example, some asserted, that if an institution does not significantly engage in retail lending and, therefore, makes few loans, the lending test should not receive more emphasis than the investment and service tests for that institution's CRA evaluation. 66 FR at 37604.

Further, some argued that an institution's record of providing services should be given more emphasis than it currently is given. Others asserted that providing services is not relevant to assessing whether an institution is meeting the credit needs of its community. 66 FR at 37604.

The 2001 ANPR asked: ''Do the regulations strike the appropriate balance between quantitative and qualitative measures, and among lending, investments, and services? If so, why? If not, how should the regulations be revised?'' 66 FR at 37604.

The 2001 ANPR also discussed, in detail, and solicited comment on, each of the component parts of the large retail institution test. With respect to the investment test, it explained that the banking agencies included the investment test in their CRA regulations in recognition that investments, as well as loans, can help meet credit needs. Some asserted, however, that the banking agencies should only consider investment activities to augment institutions' CRA ratings. In their view, although investments may help an institution to meet the credit needs of its community, particularly in low- and moderate-income areas, CRA ratings should be based primarily on lending activity. Still others stated, however, that it is inappropriate for the banking agencies to evaluate investments under the CRA as a means of meeting credit needs. Yet others argued that investments by financial institutions are invaluable in helping to meet the credit needs of the institutions' communities, particularly in low- and moderate-income areas. 66 FR at 37604–37605.

The 2001 ANPR also noted that the availability of qualified investments has been an issue of concern to some. Although some observed that, since the 1995 regulations went into effect, the market of available CRA-related investments has grown and continues to grow, others asserted that appropriate investment opportunities may not be available in their communities. Further, some of the retail institutions subject to the investment test indicated that, in some cases, it was difficult to compete for investment opportunities, particularly against much larger institutions. 66 FR at 37605.

The 2001 ANPR asked: ''Does the investment test effectively assess an institution's record of helping to meet the credit needs of its entire community? If so, why? If not, how should the regulations be revised?'' 66 FR at 37605.

With respect to the service test, the 2001 ANPR discussed issues of concern on both evaluating retail services and community development services. It asked: ''Does the service test effectively assess an institution's record of helping to meet the credit needs of its entire community? If so, why? If not, how should the regulations be revised?'' 66 FR at 37605.

In summarizing the comments on the 2001 ANPR, the preamble to the 2004 NPR indicated a majority of community organization commenters that addressed the weight given to the components of the three-part test believed that lending should continue to receive more weight than investments or services. Of financial institutions that addressed the issue, more than half agreed. The remainder of industry commenters generally believed either that the components should be weighted equally or that their weights should vary with performance context. Many financial institutions felt the investment test was weighted too heavily, while community organizations disagreed. 69 FR at 5732.

The preamble also explained that although a small number of commenters objected to any consideration of investments under CRA, the comments revealed a general view that community

development-oriented investments (''qualified investments,'' under the regulations) should be considered to the extent they help meet community credit needs. Commenters, nonetheless, disagreed significantly about whether the current investment test effectively and appropriately assesses investments and about the extent to which assessment of investments should be mandatory or optional.

As the preamble explained, financial institutions commented that the investment test is not sufficiently tailored to market reality, community needs, or institutions' capacities. Several financial institutions said there are insufficient equity investment opportunities, especially for smaller institutions and those serving rural areas. Some noted that intense competition for a limited supply of community development equity investments has depressed yields, effectively turning many of the investments into grants; some claimed that institutions had spent resources transforming would-be loans into equity investments merely to satisfy the investment test; and some expressed concern that institutions were forced to worry more about making a sufficient number and amount of investments than about the effectiveness of their investments for their communities. 69 FR at 5732–5733.

To address these concerns, many financial institutions favored abolishing the stand-alone investment test and making investments optional to one degree or another. Only two financial institutions expressly supported retaining the separate investment test. Several financial institutions and most financial institution trade associations endorsed one or more of the following three alternatives: (1) Treat investments solely as ''extra credit;'' (2) make investments count towards the lending or service test; or (3) treat investments interchangeably with community development services and loans under a new community development test. 69 FR at 5733.

In contrast, the majority of community organization commenters urged the banking agencies to retain the investment test. Many of them claimed that the problem is more often a shortage of willing investors than an insufficient number of investment opportunities. Community organizations also contended that grants and equity investments are crucial to meeting the affordable housing and economic development needs of low- and moderate-income areas and individuals. They stated, for example, that investments support and expand the capacity of nonprofit community development organizations to meet credit needs. A few community organizations acknowledged a basis for some of the financial institutions' complaints concerning the investment test, but most of those community organizations argued that refining, rather than restructuring, the large retail institution test would address such complaints. 69 FR at 5733.

The preamble to the 2004 NPR also discussed comments received on issues of concern under the service test. 69 FR at 5734–5735.

The 2004 NPR

The preamble to the 2004 NPR explained that the three-part large retail institution test places primary emphasis on lending performance, and secondary emphasis on investment and service performance. It explained in detail the reasons that the banking agencies, at that time, did not propose to eliminate the investment test, modify the service test, or change the weights given to the three tests under the large retail institution test. 69 FR at 5733–5735. Thus, it did not specifically solicit comments on these issues. Nor did the 2004 NPR propose or specifically solicit comments on the possibility of retaining all three tests as part of the large retail institution test but providing additional flexibility in the way that CRA ratings are assigned. Thus, the comments received did not focus on these possibilities either.

A few commenters on the 2004 NPR, however, indicated their continued support for creating a community development test that would incorporate all community development lending, community development investments, and community development services into a single test. A few commenters also urged the banking agencies to give more weight to certain types of services in the CRA rating.

Today's Proposal

OTS is soliciting comment on providing additional flexibility in assigning CRA ratings. The purpose would be to reduce burden while encouraging large retail savings associations to focus their community reinvestment efforts on the types of activities the communities they serve need, consistent with safe and sound operations. Rather than mandating changes to the weights assigned to lending, investments, and services under the large retail institution test, OTS is soliciting comment on providing flexibility in those weights.

This approach would serve to clarify and build upon the existing guidance currently contained in Q&A 21(b)(4)–1 discussed above addressing the application of the investment test to savings associations. Notwithstanding the Q&A and the statement in the 1995 preamble also discussed above, OTS has heard anecdotal evidence suggesting that further elaboration would be useful.

The existing guidance reflects the unique statutory and regulatory structure applicable to savings associations. Savings associations remain home mortgage lenders, in part, because unlike banks, they must have at least 65% of their assets in the form of what are generally mortgages or mortgage-related loans in order to avoid the adverse consequences of failing to meet the qualified thrift lender test under the Home Owners' Loan Act (HOLA). 12 U.S.C. 1467a(m). Savings associations are also subject to HOLA lending and investment limits, including limits on commercial loans and community development investments. 12 U.S.C. 1464(c)(2)(A) and (c)(3)(A); 12 CFR 560.30. *See* 69 FR at 51158.

To bring further clarity to the issue, OTS is considering providing each savings association evaluated under the large retail institution test a choice, at its option, on the weight given to lending, investments, and services in assessing its performance. Consistent with the traditional and appropriate emphasis on lending, OTS would not allow less than a 50 percent weight to lending. The remaining 50 percent would weigh lending, investments, or services, or some combination thereof, based on the savings association's election. As a result, each savings association could choose to have OTS weigh lending anywhere from 50% to 100% for that association's overall performance assessment, services anywhere from 0% to 50%, and investments anywhere from 0% to 50%.

As under the existing ratings matrix, OTS would continue to allocate a total of 24 possible points among the three tests. OTS would allocate 12 of these possible points to lending. OTS would allocate the remaining 12 possible points to lending, services, investments, or some combination thereof based on the savings association's weight election. For each test, the savings association would receive a percentage of the possible points it allocated to that test, with the percentage varying depending on the rating it received on that test as follows:

Rating on test	Percent of points allocated to test association would receive
Outstanding	100
High Satisfactory	75
Low Satisfactory	50
Needs to Improve	25
Substantial Noncompliance	0

For illustrative purposes, here are some examples:

1. *Lending 80% Weight, Service 10% Weight, Investment 10%*. If a savings association chose to be evaluated by OTS giving 80% weight to lending, 10% weight to services, and 10% weight to investment, OTS would apply the following matrix:

POINTS ASSIGNED FOR PERFORMANCE UNDER LENDING, INVESTMENT AND SERVICE TESTS

	Lending (80%)	Service (10%)	Investment (10%)
Outstanding	19.2	2.4	2.4
High Satisfactory	14.4	1.8	1.8
Low Satisfactory	9.6	1.2	1.2
Needs to Improve	4.8	.6	.6
Substantial Noncompliance	0	0	0

2. *Lending 50% Weight, Service 10% Weight, Investment 40%*. If a savings association chose to be evaluated by OTS giving 50% weight to lending, 10% weight to services, and 40% weight to investment, OTS would apply the following matrix:

POINTS ASSIGNED FOR PERFORMANCE UNDER LENDING, INVESTMENT AND SERVICE TESTS

	Lending (50%)	Service (10%)	Investment (40%)
Outstanding	12	2.4	9.6
High Satisfactory	9	1.8	7.2
Low Satisfactory	6	1.2	4.8
Needs to Improve	3	.6	2.4
Substantial Noncompliance	0	0	0

3. *Lending 50% Weight, Service 30% Weight, Investment 20%*. If a savings association chose to be evaluated by OTS giving 50% weight to lending, 30% weight to services, and 20% weight to investment, OTS would apply the following matrix:

POINTS ASSIGNED FOR PERFORMANCE UNDER LENDING, INVESTMENT AND SERVICE TESTS

	Lending (50%)	Service (30%)	Investment (20%)
Outstanding	12	7.2	4.8
High Satisfactory	9	5.4	3.6
Low Satisfactory	6	3.6	2.4
Needs to Improve	3	1.8	1.2
Substantial Noncompliance	0	0	0

Under all of these alternatives, the composite rating matrix would remain essentially the same as currently provided except for taking into account the possibility of fractions of points. It would read as follows:

COMPOSITE RATING POINT REQUIREMENTS

[Add points from tests as applicable]

Rating	Total points
Outstanding	20 or over.
Satisfactory	11 or more but less than 20.
Needs to Improve	5 or more but less than 11.
Substantial Non-compliance.	0 or more but less than 5.

Note: There is one exception to the Composite Rating matrix. An institution may not receive a rating of ''satisfactory'' unless it receives at least ''low satisfactory'' on the lending test. Therefore, the total points are capped at three times the lending test score.

Continuing to include the same note to the composite rating matrix as contained under the current matrix would have certain implications. For example, a savings association opting to allocate equal weight to lending as to the combination of services and investments could not receive a rating of ''satisfactory'' overall if it received a ''needs to improve'' or ''substantial noncompliance'' on its lending.

If OTS were to offer this type of flexibility, a savings association evaluated under the large retail institution test could elect weights, much in the same way as it may currently elect consideration of lending

by an affiliate or consortium, or investments or services by an affiliate. *See* 12 CFR 563e.22(c)–(d), 563e.23(c), and 563e.24(c). The Preliminary Examination Response Kit (PERK) package could be revised to provide an opportunity for a savings association to opt for an alternative weight for lending, service, and investment. Through this process, a savings association could make a new weight election at the start of each CRA examination. A savings association that did not make an election would be evaluated under the existing matrix contained in Q&A 28(a)–3.

Conforming changes could be made section 563e.28 of the CRA rule. Additional text could be added to that section indicating that a savings association could, at its option, elect to have its rating assigned under alternative weights of lending, service, and investment so long as at least 50 percent weight is given to lending.

To the extent of any inconsistency between the three rating principles in section 563e.28(b) discussed above and the rating matrix generated from the savings association's election, the standards set forth under the matrix selected would govern. Thus, for example, the principle referring to ratings on the service test and investment test would not apply to a savings association that chose not to have OTS give weight to either or both of those factors.

Providing flexibility for a savings association to elect alternative weights would supplement the use of the performance context factors discussed above and serve many of the same functions. As discussed above, OTS already evaluates a savings association's performance in the context of factors such as the savings association's product offerings and business strategy, its institutional capacity and constraints, information about lending, investment, and service opportunities in the savings association's assessment area(s), and demographic and other relevant data pertaining to a savings association's assessment area. *See* 12 CFR 563e.21(b). Likewise, providing weight alternatives would enable the savings association to have its performance evaluated in a manner most appropriately tailored to the lending, investment, and service opportunities its assessment area(s), demographic and other relevant data pertaining to its assessment area(s), its product offerings and business strategy, and its institutional capacity and constraints. This approach would be designed to encourage large retail savings associations to focus their community reinvestment efforts on the types of activities the communities they serve need, consistent with safe and sound operations.

Solicitation of Comment on Assigned Ratings Proposal

OTS solicits comments on all aspects of this proposal.

C. Solicitation of Comment on Alternative Weights Election

1. Would it be appropriate to provide the savings association flexibility in the way that CRA ratings are assigned by offering a choice of weights for the lending, service, and investment tests within the large retail institution test? If so, why? If not, why not?

2. Are there ways OTS could make the process even more flexible than outlined in this proposal?

3. What would be the impact on lending, investments, and services of offering alternative weights?

4. Should OTS place limits on the savings association's ability to opt for particular weights? How could OTS help ensure that a savings association would select weights that focus on the types of activities the communities it serves need? How could OTS take a savings association's selection of a weight alternative into consideration as part of the performance context? Is there an appropriate role for public participation beyond existing opportunities for provision of information regarding the performance context and submission of comments about the savings association's CRA performance? *See* 12 CFR 563e.21(b)(2), 563e.21(b)(6), 563e.29(c) and 563e.43(a)(1) and Q&A 21(b)(2)–2, 66 FR at 36631.

5. What logistical and practical issues would have to be addressed in providing a choice of weights and how should these issues be addressed (*e.g.*, timing and method of alternative selected)?

6. Would it be useful for OTS to publish examples of weight alternatives in the preamble to the final rule or elsewhere?

7. For ease of administrative implementation, would it be appropriate for OTS to limit the choice of weights to a list containing several options? If so, what options should be offered? Which options would a savings association be likely to choose?

8. Would it cause confusion for savings associations, community organizations, or the public to allow customized weight combinations that might be selected by only one or a few institutions (*e.g.*, lending 57%, service 28%, and investment 15%)?

9. Would it be appropriate for the alternative weights to require at least a 50 percent weight to lending, as proposed? Why or why not? If a rating matrix that gives less than 50 percent weight to lending were to be offered, would that be consistent with the purposes of CRA?

10. Would it be appropriate to continue to ensure that a savings association may not receive a rating of ''satisfactory'' unless it receives at least ''low satisfactory'' on the lending test by capping total points at three times the lending test score as under the current composite rating matrix, as proposed? Why or why not? If a rating matrix that allowed a savings association to receive a rating of ''satisfactory'' without receiving at least ''low satisfactory'' on the lending test were offered, would that be consistent with the purposes of CRA?

11. Is it appropriate to offer alternatives allowing less than a 25 percent weight to services and less than 25 percent weight to investments, as proposed? Why or why not?

D. Solicitation of Comment on Eliminating the Investment Test

1. Would a preferable alternative be to eliminate the investment test? If so, why? If not, why not?

2. What would be the impact on investments of eliminating the investment test?

3. If the investment test were eliminated as a mandatory separate component of the large retail institution test, should investments still be considered * * *

a. At a savings association's option or to raise a rating?

b. Within one of the other tests (*e.g.*, under the lending test treated similarly to community development loans)?

c. In some other fashion (*e.g.*, treating investments interchangeably with community development services and loans under a new community development test)?

4. If the investment test were eliminated as a mandatory separate component of the large retail institution test, what weight should be given to the remaining components of the test (*e.g.*, weight lending 75% and service 25%, weight lending and service 50% each)?

Regulatory Analysis

Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995, OTS may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control

number. This collection of information is currently approved under OMB Control Number 1550–0012. This proposal would not change the collection of information.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, OTS certifies that since the proposal would not have a significant economic impact on a substantial number of small entities. It would not impose any additional paperwork or regulatory reporting requirements. It would simply encourage savings associations to increase their community development lending, qualified investments, and community development services in rural areas, with a particular focus on increasing these activities in underserved nonmetropolitan areas, by expanding the definition of ''community development.'' The proposal also solicits comment on further encouraging savings associations to perform community development activities in areas affected by natural or other disasters or other major community disruptions. The other portions of the proposal relate only to the treatment of savings associations under the retail test mandated only for large institutions.

Executive Order 12866 Determination

OTS has determined that this proposal is not a significant regulatory action under Executive Order 12866.

Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (Unfunded Mandates Act) requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. OTS has determined that this rule would not result in expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more. Accordingly, OTS has not prepared a budgetary impact statement nor specifically addressed the regulatory alternatives considered.

List of Subjects in 12 CFR Part 563e

Community development, Credit, Investments, Reporting and recordkeeping requirements, Savings associations.

Office of Thrift Supervision

12 CFR Chapter V

For the reasons outlined in the preamble, the Office of Thrift Supervision proposes to amend part 563e of chapter V of title 12 of the Code of Federal Regulations as set forth below:

PART 563e—COMMUNITY REINVESTMENT

1. The authority citation for part 563e continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1814, 1816, 1828(c), and 2901 through 2907.

2. Revise § 563e.12(f)(2) and (4) to read as follows:

* * * * *

(f) *Community development* means:

* * * * *

(2) Community services targeted to low- or moderate-income individuals or to individuals in rural areas;

* * * * *

(4) Activities that revitalize or stabilize low- or moderate-income geographies or rural areas.

* * * * *

Dated: November 18, 2004.

By the Office of Thrift Supervision.

James E. Gilleran,

Director.

[FR Doc. 04–26011 Filed 11–23–04; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19681; Directorate Identifier 2003–NM–184–AD]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Model BAe 146 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all BAE Systems (Operations) Limited Model BAe 146 series airplanes. This proposed AD would require repetitive detailed inspections for cracking of the elevator ''G'' weight support structure, and repairs if necessary. This proposed AD also provides for an optional terminating action. This proposed AD is prompted by reported cracking of the elevator ''G'' weight support structure. We are proposing this AD to prevent failure of the elevator ''G'' weight support structure with possible consequent jamming of the right-hand elevator servo tab and reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by December 27, 2004.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, Room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You can get the service information identified in this proposed AD from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171.

You may examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer; International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also

lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2004–19681; Directorate Identifier 2003–NM–184–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of our docket Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may *visit http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You may examine the AD docket in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, notified us that an unsafe condition may exist on certain BAE Systems (Operations) Limited Model BAe 146 series airplanes. The CAA advises that operators have reported cracking of the elevator ''G'' weight support structure. This cracking could result from increased loading following nose wheel shimmy, overweight, hard or high drag/side load landing, flight in severe turbulence, or pitch oscillation. Cracking of the elevator ''G'' weight support structure, if not corrected, could result in failure of the elevator ''G'' weight support structure with possible consequent jamming of the right-hand elevator servo tab and reduced controllability of the airplane.

Relevant Service Information

BAE Systems (Operations) Limited has issued Inspection Service Bulletin ISB.27–037, Revision 3, dated April 17, 2003. The ISB describes procedures for repetitive detailed inspections of the elevator ''G'' weight support structure for cracking, and applicable repairs. The CAA mandated the service information and issued British airworthiness directive 006–04–2003 to ensure the continued airworthiness of these airplanes in the United Kingdom.

BAE Systems (Operations) Limited has also issued Modification Service Bulletin SB.27–037–00654A, Revision 2, dated May 8, 2003, which eliminates the need for the inspections described in ISB.27–037, Revision 3. The terminating action introduces a new elevator ''G'' weight support structure with machined castings, which replaces the existing elevator ''G'' weight support structure with light alloy pressings.

FAA's Determination and Requirements of the Proposed AD

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. We have examined the CAA's findings, evaluated all pertinent information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require repetitive detailed inspections of the elevator ''G'' weight support structure for cracking, and applicable repairs. The proposed AD would require you to use the service information described previously to perform these actions, except as discussed under ''Differences Between Proposed AD and Referenced Service Bulletins.''

This proposed AD also would provide for an optional terminating action for the repetitive inspections.

Consistent with the findings of the CAA, the proposed AD would allow repetitive inspections to continue in lieu of the terminating action. In making this determination, we considered that long-term continued operational safety in this case will be adequately ensured by repetitive inspections to detect cracking before it represents a hazard to the airplane.

Differences Between Proposed AD and British Airworthiness Directive

British airworthiness directive 006–04–2003 applies to ''Model BAe 146 pre Modification HCM00654A.'' However, we have determined that a more detailed action is required to ensure that the unsafe condition has been corrected on all Model BAe 146 airplanes. Therefore, this proposed AD applies to all Model BAe 146 series airplanes and specifies a one-time general visual inspection to determine whether Modification HCM00654A has been done. We have coordinated this difference with the CAA.

Differences Between Proposed AD and Referenced Service Bulletins

Although the referenced service bulletins describe procedures for reporting inspection results to the manufacturer, this proposed AD would not require that action. We do not need this information from operators.

Unlike the procedures described in Service Bulletin ISB.27–037, Revision 3, this proposed AD would not permit further flight if cracks are detected in the elevator ''G'' weight support structure. We have determined that, because of the safety implications and consequences associated with such cracking, any cracked elevator ''G'' weight support structure must be repaired or modified before further flight.

The service bulletins specify that you may contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require you to repair those conditions using a method that we or the CAA (or its delegated agent) approves. In light of the type of repair that would be required to address the unsafe condition, and consistent with existing bilateral airworthiness agreements, we have determined that, for this proposed AD, a repair approved by the CAA or us would be acceptable for compliance with this proposed AD.

Costs of Compliance

This proposed AD would affect about 19 airplanes of U.S. registry. The proposed actions would take about 1 work hour per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $1,235, or $65 per airplane per inspection cycle.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. *See* the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

BAE Systems (Operations) Limited (Formerly British Aerospace Regional Aircraft): Docket No. FAA–2004–19681; Directorate Identifier 2003–NM–184–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by December 27, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all BAE Systems (Operations) Limited Model BAe 146 series airplanes, certificated in any category.

Unsafe Condition

(d) This AD was prompted by reported cracking of the elevator ''G'' weight support structure. We are issuing this AD to prevent failure of the elevator ''G'' weight support structure with possible consequent jamming of the right-hand elevator servo tab and reduced controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Verification of Applicability

(f) Before the accumulation of 14,000 total landings, or within 4,000 landings after the effective date of this AD, whichever is later: Perform a one-time general visual inspection of the elevator ''G'' weight support structure to determine whether BAE Systems (Operations) Limited Modification HCM00654A as described in BAE Systems (Operations) Limited Modification Service Bulletin SB.27–037–00654A, Revision 2, dated May 8, 2003, has been incorporated on the airplane. If it can be conclusively determined that HCM00654A has been incorporated, no further action is required by this AD.

Note 1: For the purposes of this AD, a general visual inspection is ''a visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

Inspection

(g) For airplanes on which BAE Systems (Operations) Limited Modification HCM00654A has not been done and airplanes on which it cannot be conclusively determined that this modification has been done: Before the accumulation of 14,000 total landings, or within 4,000 landings after the effective date of this AD, whichever is later, except as provided by paragraph (h) of this AD, perform a detailed inspection for cracking of the elevator ''G'' weight support structure, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.27–037, Revision 3, dated April 17, 2003.

(1) If no crack is found and the structure has not been repaired previously, repeat the inspection at intervals not to exceed 4,000 landings.

(2) If no crack is found but the structure has been repaired previously, repeat the inspection at applicable intervals specified in appendix 1 of the service bulletin.

Note 2: For the purposes of this AD, a detailed inspection is ''an intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Post-Incident Inspection

(h) If, before or after any inspection required by this AD, the airplane experiences any incident of nose wheel shimmy, overweight, hard or high drag/side load landing, flight in severe turbulence, or pitch oscillation; before further flight, repeat the inspection required by paragraph (g) of this AD. If no crack is found, repeat the inspection required by paragraph (g)(1) or (g)(2) of this AD, as applicable.

Corrective Actions

(i) If any crack is found during any inspection required by paragraph (g) or (h) of this AD, before further flight, replace the elevator ''G'' weight support structure in accordance with paragraph (j) of this AD, or repair the structure in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, or the Civil Aviation Authority (CAA) (or its delegated representative).

Optional Terminating Action

(j) Replacement of the existing elevator ''G'' weight support structure with a new, improved elevator ''G'' weight support structure in accordance with BAE Systems (Operations) Limited Modification Service Bulletin SB.27–037–00654A, Revision 2, dated May 8, 2003, terminates the repetitive inspections required by paragraph (g) of this AD.

No Reporting Requirement

(k) Although the service bulletins referenced in this AD specify to submit certain information to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance

(l) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, is authorized to approve alternative methods of compliance for this AD.

Related Information

(m) British airworthiness directive 006–04–2003 also addresses the subject of this AD.

Issued in Renton, Washington, on November 10, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26032 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19682; Directorate Identifier 2004–NM–88–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–600, –700, –700C, –800 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 737–600, –700, –700C, and –800 series airplanes. This proposed AD would require inspecting/measuring the length of the attachment fasteners between the nacelle support fittings and the lower wing skin panels, and related investigative/corrective actions if necessary. This proposed AD is prompted by a report from the manufacturer that in production, during the installation of certain attachment fasteners for the nacelle support fittings, only one washer was installed instead of two. We are proposing this AD to prevent inadequate fastener clamp-up, which could result in cracking of the fastener holes, cracking along the lower wing skin panels, fuel leaking from the wing fuel tanks onto the engines, and possible fire.

DATES: We must receive comments on this proposed AD by January 10, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, Room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Robert Hardwick, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6457; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19682; Directorate Identifier 2004–NM–88–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that website, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You may examine the AD docket in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received a report indicating that, during the production of certain Boeing Model 737–600, –700, –700C, and –800 series airplanes, it was discovered that certain attachment fasteners that attach the nacelle support fittings to the lower wing skin panels were improperly installed. The affected fasteners were installed during production with only one washer instead of two, which could cause the nut to tighten against the thread runout on the fastener shank rather than clamping the joint. This condition can be identified by checking the thread protrusion between the top of the nut and the end of the fastener to determine if the thread protrusion is outside of the limits specified by the manufacturer. Discrepant thread protrusion could indicate inadequate clamp-up between the nacelle support fittings and the lower wing skin panels. Adequate clamp-up compresses the components together, which assists in preventing cracking. Inadequate clamp-up, if not corrected, could result in cracking of the fastener holes, cracking along the lower wing skin panels, fuel leaking from the wing fuel tanks onto the engines, and possible fire.

Relevant Service Information

We have reviewed Boeing Service Bulletin 737–57–1275, dated September 4, 2003. The service bulletin describes procedures for inspecting/measuring the thread protrusion of certain attachment fasteners between the lower wing skin panels and the nacelle support fittings, marking fasteners with measurements outside of the specified thread protrusion limits, and related investigative and corrective actions. For fasteners with measurements outside of

the specified limits, the related investigative actions include reaming the affected fastener holes and doing a high frequency eddy current inspection of the complete fastener hole stack-up for cracking. If no cracking is found, the corrective actions include reaming the holes to the next nominal diameter and installing new fasteners. If cracking is found, the service bulletin specifies contacting Boeing for repair information. For repaired areas, the service bulletin also specifies doing fuel leak inspections. Accomplishing the actions specified in the service bulletin will adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require inspecting/measuring the length of the attachment fasteners between the nacelle support fittings and the lower wing skin panels, and related investigative/corrective actions if necessary. The proposed AD would require you to use the service information described previously to perform these actions, except as discussed under ''Differences Between the Proposed AD and Service Information.''

Differences Between the Proposed AD and Service Information

The service bulletin states that the inspection/measurement should be done within 30,000 flight cycles or 30,000 flight hours from airplane delivery, whichever is first. For airplanes not modified by Supplemental Type Certificate (STC) ST00830SE, this proposed AD specifies doing the inspection/measurement prior to the accumulation of 30,000 total flight cycles or 30,000 total flight hours, whichever is first. For airplanes modified by that STC, the proposed AD specifies doing the inspection/measurement prior to the accumulation of 25,000 total flight cycles or 25,000 total flight hours, whichever is first. The STC is an airplane modification that installs winglets. We have determined that airplanes with winglets have increased wing loads, which could result in cracking at a lower threshold than airplanes without winglets.

The service bulletin also specifies that you may contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require you to repair those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the type certification basis of the airplane, and that have been approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

Costs of Compliance

This proposed AD would affect about 751 airplanes worldwide. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection/Measurement	12	$65	Nominal	$780	302	$235,560

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19682; Directorate Identifier 2004–NM–88–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by January 10, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 737–600, –700, –700C, and –800 series airplanes; line numbers 1 through 761 inclusive, except for line numbers 596, 683, 742, 749, 750, 751, 754, 755, 759, and 760; certificated in any category;

Unsafe Condition

(d) This AD was prompted by a report from the manufacturer that in production, during installation of certain attachment fasteners for the nacelle support fittings, only one washer was installed instead of two. We are issuing this AD to prevent inadequate fastener clamp-up, which could result in cracking of the fastener holes, cracking along the lower wing skin panels, fuel leaking from the wing fuel tanks onto the engines, and possible fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection/Measurement and Related Investigative and Corrective Actions

(f) At the applicable time specified in paragraph (f)(1) or (f)(2) of this AD: Inspect/measure the length of certain attachment fasteners between the lower wing skin panels and the nacelle support fittings. Do the inspection/measurement, and all applicable

related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–57–1275, dated September 4, 2003, except as provided by paragraph (g) of this AD.

(1) For airplanes modified by Supplemental Type Certificate (STC) ST00830SE as of the effective date of this AD: Prior to the accumulation of 25,000 total flight hours or 25,000 total flight cycles, whichever is first.

(2) For airplanes not modified by STC ST00830SE as of the effective date of this AD: Prior to the accumulation of 30,000 total flight hours or 30,000 total flight cycles, whichever is first.

(g) If accomplishing a corrective action as required by paragraph (f) of this AD, and the service bulletin specifies to contact Boeing for repair information: Before further flight, do the repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on November 10, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26031 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19676; Directorate Identifier 2004–NM–138–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–135 and –145 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain EMBRAER Model EMB–135 and –145 series airplanes. This proposed AD would require determining the torque values of the screws that attach the seat tracks to the airplane, and corrective action if necessary. This proposed AD is prompted by a report of undertorqued screws. We are proposing this AD to prevent improper torque of those screws, which in the case of a hard landing or a high deceleration impact condition could result in damage to the seat and possible subsequent injury to the passenger.

DATES: We must receive comments on this proposed AD by December 27, 2004.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: *Technical information:* Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19676; Directorate Identifier 2004–NM–138–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of our docket website, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT

street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

The Departmento de Aviacao Civil (DAC), which is the airworthiness authority for Brazil, notified us that an unsafe condition may exist on certain EMBRAER Model EMB–135 and –145 series airplanes. The DAC advises that some screws that attach the passenger seat tracks had been undertorqued during manufacture. This condition, if not corrected, could result in damage to the seat and possible subsequent injury to the passenger.

Relevant Service Information

EMBRAER has issued Service Bulletins 145LEG–53–0015 (for Model EMB–135 BJ series airplanes) and 145–53–0049 (for Model EMB–135 and –145 series airplanes), both dated February 16, 2004. The service bulletins describe procedures for inspecting for proper torque of the screws that attach the seat tracks to the airplane, retorquing the screws if necessary, and applying torque seal. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The DAC mandated the service information and issued Brazilian airworthiness directive 2004–05–03, dated June 2, 2004, to ensure the continued airworthiness of these airplanes in Brazil.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in Brazil and are type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DAC has kept the FAA informed of the situation described above. We have examined the DAC's findings, evaluated all pertinent information, and determined that we need to issue an AD for products of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Airplane(s)	Work hours	Average labor rate/hour	Parts	Cost/airplane
EMB–135 BJ	24	$65	Minimal	$1,560
Others	28	65	Minimal	1,820

The cost for the U.S. fleet of 539 airplanes would be $840,840 to $980,980, depending on the airplane model.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Empresa Brasileira De Aeronautica S.A. (EMBRAER): Docket No. FAA–2004–19676; Directorate Identifier 2004–NM–138–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by December 27, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to EMBRAER Model EMB–135 and –145 series airplanes, certificated in any category; as listed in EMBRAER Service Bulletin 145LEG–53–0015 or 145–53–0049, both dated February 16, 2004.

Unsafe Condition

(d) This AD was prompted by a report indicating that some screws that attach the passenger seat tracks were undertorqued. We are issuing this AD to prevent improper torque of those screws, which in the case of a hard landing or a high deceleration impact condition could result in damage to the seat and possible subsequent injury to the passenger.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection

(f) Within 5,000 flight hours or 36 months after the effective date of this AD, whichever occurst first, determine the torque values of the screws that attach the seat tracks to the airplane. Use EMBRAER Service Bulletin 145LEG–53–0015 (for Model EMB–135 BJ series airplanes) or 145–53–0049 (for the remaining affected airplanes), both dated February 16, 2004, to do the inspection. Before further flight, retorque any screw having improper torque and apply torque seal to all the screws, in accordance with the service bulletin.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(h) Brazilian airworthiness directive 2004–05–03, dated June 2, 2004, also addresses the subject of this AD.

Issued in Renton, Washington, on November 10, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26030 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19680; Directorate Identifier 2003–NM–215–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 767 series airplanes. This proposed AD would require performing a test of the bonding resistance between the engine fuel feed tube fitting and the front spar, applying sealant on a hex nut inside the dry bay, and performing any applicable corrective actions. This proposed AD is prompted by a report that the engine fuel feed tubes were found not electrically bonded to the front spar. We are proposing this AD to prevent an ignition source from entering the fuel tank during a lightning strike event, which could cause a fuel tank explosion.

DATES: We must receive comments on this proposed AD by January 10, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: *Technical Information:* Bernie Gonzalez, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6498; fax (425) 917–6590.

Plain Language Information: Marcia Walters, *marcia.walters@faa.gov*.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19680; Directorate Identifier 2003–NM–215–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that website, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket in person at the Docket Management Facility office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received a report that, during electrical bonding and grounding tests of penetrations on the wing fuel tanks of Boeing Model 747 series airplanes, the feed tubes for the engine fuel were found not electrically bonded to the front spar. The same condition was found on Model 767 series airplanes; Model 737–100, –200, –200C, –300, –400, and –500 series airplanes; and Model 707 series airplanes. This condition, if not corrected, could result in an ignition source entering the fuel tank during a lightning strike event, which could cause a fuel tank explosion.

Other Relevant Rulemaking

We previously issued AD 2004–10–06, amendment 39–13636 (69 FR 28046, May 18, 2004), applicable to Model 747 series airplanes; Model 737–100, –200, –200C, –300, –400, and –500 series airplanes; and Model 727–100, and –200 series airplanes. That AD was issued to ensure that the similar unsafe condition (hydraulic heat exchanger tube penetration fittings were found not electrically bonded to the fuel tank rear spar) was repaired. That AD requires, among other things, preparation of the electrical bonding faying surfaces for the tubing penetrations of the hydraulic

heat exchanger on the forward and aft surfaces of the rear spars of the fuel tanks of the left and right wings, a one-time measurement of the electrical bonding resistances, and follow-on actions.

We have also published a proposal to amend 14 CFR Part 39 with an AD for certain Boeing Model 707–100, –100B, –300, –300B (–320B variant), –300C, and –E3A (military) series airplanes; Model 720, and 720B series airplanes; Model 737–100, –200, –200C, –300, –400, and –500 series airplanes; and Model 747 series airplanes in the **Federal Register** on August 4, 2004 (69 FR 47031). That action proposed to require repetitive tests of the overwing fuel fill ports for certain wing tanks; an electrial bonding resistance test between the bulkhead fittings of the engine fuel feed tube and the front spar inside the fuel tank of the wings; other specified actions; and applicable corrective actions if necessary.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletins 767–28A0071, Revision 1 (for Model 767–200, –300, and –300F series airplanes), and 767–28A0072, Revision 1 (for Model 767–400ER series airplanes); both dated January 22, 2004. These service bulletins describe procedures for doing a test to determine the bonding resistance between the engine fuel feed tube fitting and the front spar, applying sealant on a hex nut inside the dry bay, and doing corrective actions if necessary. The corrective actions include applying sealant inside and outside the fuel tube bulkhead fitting and coupling, reworking the bonding path, and checking the fuel feed tubes for leaks. Accomplishment of the actions specified in the applicable service bulletin is intended to adequately address the identified unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require performing a test of the bonding resistance between the engine fuel feed tube fitting and the front spar, applying sealant on a hex nut inside the dry bay, and performing any applicable corrective actions. The proposed AD would require you to use the service information described previously to perform these actions.

Costs of Compliance

There are about 867 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 400 airplanes of U.S. registry. The proposed actions would take about 3 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $78,000, or $195 per airplane.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19680; Directorate Identifier 2003–NM–215–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by January 10, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 767–200, –300, and –300F series airplanes, as identified in Boeing Alert Service Bulletin 767–28A0071, Revision 1, dated January 22, 2004; and Model 767–400ER series airplanes as identified in Boeing Alert Service Bulletin 767–28A0072, Revision 1, dated January 22, 2004; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report that the engine fuel feed tubes were found not electrically bonded to the front spar. We are issuing this AD to prevent an ignition source from entering the fuel tank during a lightning strike event, which could cause a fuel tank explosion.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Service Bulletin Definition

(f) The term ''service bulletin,'' as used in this AD, means the Work Instructions of the following service bulletins, as applicable:

(1) For Model 767–200, –300, and –300F series airplanes: Boeing Alert Service Bulletin 767–28A0071, Revision 1, dated January 22, 2004; and

(2) For Model 767–400ER series airplanes: Boeing Alert Service Bulletin 767–28A0072, Revision 1, dated January 22, 2004.

Investigative and Corrective Actions

(g) Within 48 months after the effective date of this AD: Do a test of the bonding resistance between the engine fuel feed tube fitting and the front spar, apply sealant on a hex nut inside the dry bay, and do any applicable corrective actions, by accomplishing all of the actions in the applicable service bulletin. Do any applicable corrective actions before further flight.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on November 10, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26029 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19679; Directorate Identifier 2003–NM–132–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes. This proposed AD would require repetitive inspections of the carriage attach fittings on the foreflaps of each wing for cracking and other discrepancies, and corrective actions if necessary. For certain airplanes, the proposed AD would also concurrently require various other actions related to the subject area. This proposed AD also provides for an optional terminating action for the repetitive inspection requirements and for an optional replacement that would defer the repetitive inspections. This proposed AD is prompted by reports of damaged or failed outboard foreflaps with a cracked or failed carriage attach fitting of the foreflap sequencing carriage. We are proposing this AD to detect and correct fatigue cracking of the attach fittings of the foreflap carriage of the wings, which could result in partial or complete loss of the foreflap and consequent loss of controllability of the airplane.

DATES: We must receive comments on this proposed AD by January 10, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19679; the directorate identifier for this docket is 2003–NM–132–AD.

FOR FURTHER INFORMATION CONTACT: *Technical information:* Daniel F. Kutz; Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6456; fax (425) 917–6590..

Plain language information: Marcia Walters, *marcia.walters@faa.gov*.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19679; Directorate Identifier 2003–NM–132–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that website, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at http://dms.dot.gov, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received several reports of damaged or failed outboard foreflaps with a cracked or failed carriage attach fitting of the foreflap sequencing carriage on certain Boeing Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes. Investigation revealed that fatigue cracking of the fitting is possible due to high fit-up stress combined with airloads. Such fatigue cracking, if not detected and corrected, could result in partial or complete loss of the foreflap and consequent loss of controllability of the airplane.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002. The service bulletin describes the following inspection and corrective procedures for the two carriage attach fittings on the inboard and outboard foreflaps of each wing:

- Repetitive detailed inspections to detect cracks and surface deviations on all edges, surfaces, and lug attachment fastener holes;

• Repetitive high frequency eddy current inspections (HFEC) to detect cracks at the lug attachment fastener holes; and

• For cases where any crack is detected at a lug attachment fastener hole or any surface deviation beyond certain limits is detected on any edge, surface, or lug attachment fastener hole: Replacement of that carriage attach fitting with a new, improved fitting or a new fitting having the same part number as the existing fitting.

The service bulletin also describes the following two optional procedures:

• Replacing the two carriage attach fittings on the inboard and outboard foreflaps of each wing with a new, improved fitting. Accomplishment of this replacement and the applicable procedures specified in Boeing Service Bulletin 57–59, Revision 1, dated September 27, 1965; Boeing Service Bulletin 727–27–133, Revision 1, dated May 9, 1972; and Boeing Service Bulletin 57–72, dated September 21, 1966 (all three described below); as applicable; would eliminate the need for the repetitive inspections described above.

• Replacing the two carriage attach fittings on the inboard and outboard foreflaps of each wing with new fittings having the same part number as the existing fittings. Accomplishment of this replacement and the applicable procedures specified in Boeing Service Bulletins 57–59, 727–27–133, and 57–72 would defer the next inspections described above for an additional 10,000 flight cycles.

In addition, the service bulletin also describes procedures for inspecting for interference between the carriage attach fitting and the carriage lug fitting, and other related investigative/corrective actions if necessary. The related investigative actions include measuring the radius for minimum permitted radius and inspecting surface finish for maximum permitted finish. The corrective actions include adding a shim; reworking the carriage attach lug; and contacting the airplane manufacturer if rework of the improved fitting is required; as applicable.

We have also reviewed Boeing Service Bulletin 57–59, Revision 1, dated September 27, 1965. The service bulletin describes procedures for installation of guide blocks and bushings in the midflap ribs.

In addition, we have reviewed Boeing Service Bulletin 727–27–133, Revision 1, dated May 9, 1972. The service bulletin describes procedures for performing a one-time inspection for foreflap airload roller travel on the foreflap track; repair if necessary; and modifying the control drum of the inboard flap and inboard jackscrews of the outboard flap; as applicable. The modification includes installing a stop plate on the control drum of the inboard flap, and replacing the down stop at the inboard jackscrews of the outboard flap; as applicable.

In addition, we have reviewed Boeing Service Bulletin 57–72, dated September 21, 1966. The service bulletin describes procedures for chamfering the upper and lower flanges at the aft end of the foreflap tracks; performing a standard magnetic particle inspection of the entire foreflap tracks for cracks; performing a one-time general inspection of the track rib faces to verify if the opening in the spars is flush with or clear of the plane of the track rib faces; and rework if necessary. This rework includes trimming the midflap front and rear spar webs. The service bulletin also describes procedures for a one-time general visual inspection of the head or shank of bolts by securing the foreflap links to the foreflap tracks to verify if they protrude beyond the edge of the track flange, and rework if necessary. This rework includes installing a laminated washer under the bolt head.

Accomplishing the actions specified in the service information described above is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require repetitive inspections of the carriage attach fittings on the foreflaps of each wing for cracking and other discrepancies, and corrective actions if necessary. For certain airplanes, the proposed AD would also concurrently require various other actions related to the subject area. This AD also provides for an optional terminating action for the repetitive inspection requirements and for an optional replacement that would defer the repetitive inspections. The actions, if accomplished, would be required to be accomplished in accordance with the service bulletins described previously, except as discussed under ''Difference Between the Proposed AD and Service Bulletins.''

Difference Between the Proposed AD and Service Bulletins

Boeing Alert Service Bulletin 727–57A0135 and Boeing Service Bulletin 727–27–133 specify that the manufacturer may be contacted for disposition of certain rework and repair conditions. In addition, Boeing Service Bulletin 57–72 does not specify what to do for cases of crack findings during a standard magnetic particle inspection of the entire foreflap tracks. However, unlike those service bulletins, this proposal would require the rework and repair of those conditions to be accomplished in accordance with a method approved by the FAA, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

Costs of Compliance

There are about 1,292 airplanes of the affected design in the worldwide fleet. We estimate that 855 airplanes of U.S. registry would be affected by this proposed AD. The average labor rate is $65 per work hour. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

For	Action	Work hours	Parts cost	Cost
All airplanes	Inspections of the carriage attach fittings	4	None	$222,300, $260 per airplane, per inspection cycle.
Certain airplanes	Installation of guide blocks	32	Free	$2,080 per airplane.
Certain airplanes	Inspection of foreflap airload roller travel	4	None	$260 per airplane.
Certain airplanes	Modification of the inboard jackscrews on the outboard flap.	4	Free	$260 per airplane.
Certain airplanes	Inspection of the entire track and of the track rib faces.	12	None	$780 per airplane.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19679; Directorate Identifier 2003–NM–132–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by January 10, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes, as listed in Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of damaged or failed outboard foreflaps with a cracked or failed carriage attach fitting of the foreflap sequencing carriage. We are issuing this AD to detect and correct fatigue cracking of the attach fittings of the foreflap carriage of the wings, which could result in partial or complete loss of the foreflap and consequent loss of controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspections

(f) Except as provided by paragraph (o) of this AD: Within 1,000 flight cycles after the effective date of this AD, and thereafter at intervals not to exceed 1,000 flight cycles, inspect as specified in paragraphs (f)(1) and (f)(2) of Table 1 of this AD in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002. Table 1 is as follows:

TABLE 1.—INSPECTION REQUIREMENTS

Requirements—	Description—
(1) Area to inspect	The two carriage attach fittings on the inboard and outboard foreflaps of each wing.
(2) Type of inspections	(i) A detailed inspection to detect cracks and surface deviations on all edges, surfaces, and lug attachment fastener holes. (ii) A high frequency eddy current (HFEC) inspection to detect cracks at the lug attachment fastener holes.

Crack or Surface Deviation Findings: Replacement

(g) If any crack is detected or if any surface deviation beyond the limits specified in the service bulletin is detected during any inspection required by paragraph (f) of this AD, before further flight, replace the carriage attach fitting with a new, improved fitting or a new fitting having the same part number as the existing fitting, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002.

Measurement and Associated Corrective Action(s)

(h) Within 3,500 flight cycles after the effective date of this AD, inspect for interference between the carriage attach fitting and the carriage lug fitting, and do other related investigative actions by accomplishing all the actions specified in paragraph 3.C. and Figure 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002. Do the actions in accordance with the service bulletin.

(i) If any discrepancy is found during any action required by paragraph (h) of this AD, before further flight, accomplish applicable corrective action(s) (*e.g.,* adding a shim or reworking the carriage attachment lug assembly) in accordance with paragraph 3.C. and Figure 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002. Where the service bulletin specifies to contact the manufacturer if rework of the improved fitting is required: Before further flight, rework in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the FAA to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

Concurrent Requirements

(j) For Model 727 airplanes listed in Boeing Service Bulletin 57–59, Revision 1, dated September 27, 1965: Before or at the same time with the requirements of paragraph (h) of this AD, install guide blocks and bushings in the midflap ribs in accordance with the Accomplishment Instructions of the service bulletin.

(k) For Model 727 airplanes listed in Boeing Service Bulletin 727–27–133, Revision 1, dated May 9, 1972: Before or at the same time with the requirements of paragraph (h) of this AD, do the actions specified in paragraphs (k)(1) and (k)(2) of this AD, as applicable.

(1) For Groups I and II airplanes identified in the service bulletin: Do a one-time inspection of the airload support roller for travel on the foreflap track in accordance with Part I of the Accomplishment Instructions of the service bulletin.

(i) If the airload support roller travels within the limits specified in the service bulletin, modify the control drum of the inboard flap and inboard jackscrews of the outboard flap, in accordance with Part II of the Accomplishment Instructions of the service bulletin.

(ii) If the airload support roller travels beyond the limits specified in the service bulletin, repair in accordance with a method approved by the Manager, Seattle ACO, FAA or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the FAA to make such findings.

(2) For Group III airplanes identified in the service bulletin: Modify the inboard jackscrews of the outboard flap (*i.e.*, replacing the down stop at the inboard jackscrews of the outboard flap) in accordance with Part II of the Accomplishment Instructions of the service bulletin.

(l) For Model 727 airplanes listed in Boeing Service Bulletin 57–72, dated September 21, 1966: Before or at the same time with the requirements of paragraph (h) of this AD, do the actions specified in paragraphs (l)(1) through (l)(4) of this AD.

(1) Chamfer the upper and lower flanges at the aft end of the foreflap tracks in accordance with the Accomplishment Instructions of the service bulletin.

(2) Do a standard magnetic particle inspection of the entire foreflap tracks for cracks in accordance with the Accomplishment Instructions of the service bulletin. If any crack is detected, before further flight, repair in accordance with a method approved by the Manager, Seattle ACO, FAA or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the FAA to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

(3) Do a general visual inspection of the track rib faces at the front and rear spars to verify if the opening in the spars is flush with or clear of the plane of the rib faces, in accordance with the Accomplishment Instructions of the service bulletin. If the opening is not flush or clear with the plane, before further flight, rework the spar opening in accordance with the Accomplishment Instructions of the service bulletin.

(4) Do a general visual inspection of the head or shank of bolts by securing the foreflap links to the foreflap tracks to verify if they protrude beyond the edge of the track flange in accordance with the Accomplishment Instructions of the service bulletin. If the head or shank of the bolts protrude beyond the edge of the track flange, before further flight, rework in accordance with the Accomplishment Instructions of the service bulletin.

Note 1: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(m) For airplanes other than those identified in the service bulletins specified in paragraphs (j) through (l) of this AD: Before or at the same time with the requirements of paragraph (h) of this AD, do an inspection to verify if any of the parts listed in the ''Spares Affected'' paragraph of each service bulletin referenced in paragraphs (j) through (l) of this AD are installed on the airplane. If any part identified in that paragraph is found installed, before further flight, do the applicable corrective and investigative action(s) specified in paragraphs (j) through (l) of this AD.

Optional Terminating Actions

(n) Replacement of the two carriage attach fittings on the inboard and outboard foreflaps of each wing with new, improved fittings, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002; and accomplishment of the actions specified in paragraphs (j) through (m) of this AD, as applicable, before or concurrently with the replacement; constitutes terminating action for the requirements of this AD.

Optional Deferral of Inspection

(o) Replacement of the two carriage attach fittings on the inboard and outboard foreflaps of each wing with new fittings having the same part number as the existing fittings, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 727–57A0135, Revision 3, dated June 27, 2002; and accomplishment of the actions specified in paragraphs (j) through (m) of this AD, as applicable, before or concurrently with the replacement; defers the next inspection required by paragraph (f) of this AD for 10,000 flight cycles after the replacement. Thereafter, repeat the inspections required by paragraph (f) of this AD at intervals not to exceed 1,000 flight cycles.

Credit for Previously Accomplished Service Bulletins

(p) Installations accomplished before the effective date of this AD in accordance with Boeing Service Bulletin 57–59, dated September 2, 1965; are acceptable for compliance with the requirements of paragraph (j) of this AD.

(q) Inspections and modifications accomplished before the effective date of this AD in accordance with Boeing Service Bulletin 727–27–133, dated October 7, 1971; are acceptable for compliance with the requirements of paragraph (k) of this AD.

Alternative Methods of Compliance (AMOCs)

(r)(1) In accordance with 14 CFR 39.19, the Manager, Seattle ACO, FAA, is authorized to approve alternative methods of compliance for this AD.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on November 19, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26028 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19678; Directorate Identifier 2004–NM–62–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–400F Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 747–400F series airplanes. This proposed AD would require initial detailed and open-hole high frequency eddy current inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, and repair of any cracking. This proposed AD also would require a preventive modification of the upper deck floor beams, and repetitive inspections for cracking after accomplishing the modification. This proposed AD is prompted by reports of fatigue cracking found on the upper deck floor beam to frame attachment points. We are proposing this AD to prevent fatigue cracks in the upper chord, upper chord strap, and the web of the upper deck floor beams and resultant failure of the floor beams. Failure of a floor beam could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by January 10, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, Room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: *Technical information:* Ivan Li, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6437; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2004–19678; Directorate Identifier 2004–NM–62–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can *visit http://dms.dot.gov.*

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Related Rulemaking

On January 29, 2004, we issued AD 2004–03–11, amendment 39–13455 (69 FR 5920, February 9, 2004). That AD applies to certain Boeing Model 747–200C and –200F series airplanes, and requires repetitive inspections to find fatigue cracking in the upper chord of the upper deck floor beams, and repair if necessary. For certain airplanes, that AD also provides an optional repair/modification, which defers certain repetitive inspections.

Actions Since Issuance of Previous Rulemaking

Since issuance of AD 2004–03–11, we have received reports indicating that additional fatigue cracking was found on the upper deck floor beam to frame attachment points, on certain Model 747–200F series airplanes. The upper deck floor beams on certain 747–400F series airplanes are similar to those on the affected 747–200F series airplanes. In light of these reports, we have determined that it is necessary to issue the proposed AD at this time to ensure the continued operating safety of the affected airplane fleet. Therefore, all of these models may be subject to the same unsafe condition. Failure of a floor beam due to fatigue cracking could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of the airplane.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 747–53A2443, dated May 9, 2002. The service bulletin describes procedures for a detailed inspection for cracking of the web, upper chord and upper chord strap of body stations 340 through 520 inclusive, of the upper deck floor beams; an open-hole high frequency eddy current (HFEC) inspection for cracking of the fastener holes of the web, upper chord, and upper chord strap; and repair of any cracking. If any cracking is found, the procedures in the service bulletin include repairing the cracking and accomplishing a preventive modification before further flight, or contacting the manufacturer for repair instructions if the cracking exceeds certain limits.

If no cracking is found, the procedures in the service bulletin include two options: Modifying the upper chord of the upper deck floor beams before further flight, or repeating the detailed and open-hole inspections before the accumulation of 20,000 total flight cycles, then accomplishing the preventive modification before further flight. Accomplishing the preventive modification extends the compliance time for the next detailed and open-hole or surface HFEC inspections of the upper deck floor beams to 15,000 flight cycles after accomplishing the modification.

For the post-modification inspection, the service bulletin gives the option of either repeating the detailed and surface HFEC inspections every 1,000 flight cycles, or repeating the detailed and open-hole HFEC inspections every 5,000 flight cycles.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require initial detailed and open-hole HFEC inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, and repair of any cracking. The proposed AD also would require a preventive modification of the upper deck floor beams, and repetitive inspections for cracking after accomplishing the modification. The proposed AD would require you to use the service information described previously to perform these actions, except as discussed under ''Differences Between the Alert Service Bulletin and This Proposed AD.''

Differences Between the Alert Service Bulletin and This Proposed AD

The service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions, but this proposed AD would require the repair of those conditions to be accomplished in accordance with a method approved by the FAA, or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

The service bulletin refers to a ''detailed visual inspection'' for cracking of the web, upper chord, and strap of the upper deck floor beams. We have determined that the procedures in the service bulletin should be described as a ''detailed inspection.'' Note 1 has been included in this proposed AD to define this type of inspection.

Although the service bulletin does not list a grace period in the compliance times for the initial inspections and the preventive modification, this proposal adds a grace period to those compliance times. We find that such a grace period will keep airplanes from being grounded unnecessarily.

Costs of Compliance

This proposed AD would affect about 53 airplanes worldwide and 13 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD, depending on the airplane configuration:

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of affected U.S.-registered airplanes	Fleet cost
Pre-modification/inspections.	11	$65	$0	$715	13	$9,295.
Modification/Inspections done during modification.	498 or 524	65	13,554 or 14,874	45,924 or 48,934.	13	597,012 or 636,142.
Post-modification inspections.	66	65	0	4,290, per inspection cycle.	13	55,770.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19678; Directorate Identifier 2004–NM–62–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by January 10, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Model 747–400F series airplanes, certificated in any category; as listed in Boeing Alert Service Bulletin 747–53A2443, dated May 9, 2002.

Unsafe Condition

(d) This AD was prompted by reports of fatigue cracking found on the upper deck floor beam to frame attachment points. We are issuing this AD to prevent fatigue cracks in the upper chord, upper chord strap, and web of the upper deck floor beams and the resultant failure of the floor beams. Failure of a floor beam could result in damage to critical flight control cables and wire bundles that pass through the floor beam, and consequent loss of controllability of the airplane. Failure of the floor beam also could result in the failure of the adjacent fuselage frames and skin, and consequent rapid decompression of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Service Bulletin Reference

(f) For the purposes of this AD, the term ''service bulletin'' means the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2443, dated May 9, 2002.

Inspections/Repair/Modification

(g) Before the accumulation of 15,000 total flight cycles, or within 1,000 flight cycles after the effective date of this AD, whichever is later: Accomplish detailed and open-hole high frequency eddy current (HFEC) inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, by doing all the applicable actions in accordance with Part 3.B.1. of the service bulletin.

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

(h) If any crack is found during any inspection required by paragraph (g) of this AD: Before further flight, accomplish the actions required by paragraph (h)(1) and (h)(2) of this AD.

(1) Repair in accordance with the service bulletin; except where the service bulletin specifies to contact Boeing for appropriate action, before further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or according to data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

(2) Accomplish the inspections and preventive modification of the floor beams by doing all the actions in accordance with Part 3.B.2. or Part 3.B.3. of the service bulletin, as applicable. If any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

(i) If no crack is found during any inspection required by paragraph (g) of this AD: Accomplish the actions required by either paragraph (i)(1) or (i)(2) of this AD, at the time specified.

(1) Before further flight: Accomplish the inspections and preventive modification of the floor beam by doing all the actions in accordance with Part 3.B.2 or Part 3.B.3. of the service bulletin, as applicable. If the preventive modification is performed concurrently with the inspections required by paragraph (g) of this AD, the upper chord straps must be removed when performing the open-hole HFEC inspection. If any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

(2) Before the accumulation of 20,000 total flight cycles, or within 1,000 flight cycles after the effective date of this AD, whichever is later: Accomplish the inspections and preventive modification of the upper deck floor beams, by doing all the actions in accordance with Part 3.B.2. or 3.B.3. of the service bulletin, as applicable. If any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

Post-Modification Inspections

(j) Within 15,000 flight cycles after accomplishing the applicable preventive modification required by paragraph (h)(2), (i)(1), or (i)(2) of this AD: Accomplish the inspections required by either paragraph (j)(1) or (j)(2) of this AD; if any crack is found during any inspection, before further flight, repair as required by paragraph (h)(1) of this AD.

(1) Accomplish detailed and surface HFEC inspections for cracking of the web, upper chord, and upper chord strap of the upper deck floor beams, by doing all the applicable actions in accordance with Part 3.B.4. of the service bulletin. If no crack is found, repeat the inspections at intervals not to exceed 1,000 flight cycles.

(2) Accomplish detailed and open-hole HFEC inspections for cracking of the web, upper chord, and strap of the upper deck floor beams, by doing all the applicable actions in accordance with Part 3.B.5. of the service bulletin. If no crack is found, repeat the inspections at intervals not to exceed 5,000 flight cycles.

Note 2: There is no terminating action currently available for the repetitive inspections required by this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on November 10, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–26027 Filed 11–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 2004N–0461]

Environmental Assessment; Categorical Exclusions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation on environmental impact considerations to expand existing categorical exclusions to include approvals of humanitarian device exemptions (HDEs) and establishment of special controls as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an environmental assessment (EA) nor environmental impact statement (EIS) is required. Regulations issued by the Council on Environmental Quality require that all Federal Agencies assess the environmental impact of their major actions and ensure that the interested and affected public is informed of environmental analyses. FDA is taking this action in accordance with the National Environmental Policy Act (NEPA).

DATES: Submit written or electronic comments on the proposed rule by December 27, 2004. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

ADDRESSES: You may submit comments, identified by 2004N–0461, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include [Docket No. 2004N–0461] in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No(s). or Regulatory Information

Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–2970.

SUPPLEMENTARY INFORMATION:

I. National Environmental Policy Act

NEPA requires all Federal Agencies to assess the environmental impact of major actions and to ensure that the interested and affected public is informed of environmental analyses. The Council on Environmental Quality (CEQ) is responsible for overseeing Federal efforts to comply with NEPA. Both CEQ and FDA have issued regulations governing agency obligations and responsibilities under NEPA. In the **Federal Register** of March 15, 1973 (38 FR 7001), FDA issued its first regulations to implement NEPA. FDA amended these regulations in the **Federal Register** of April 15, 1977 (42 FR 19986), based on consideration of revised guidelines for preparing EISs issued by CEQ. In 1978, CEQ replaced its guidelines with regulations implementing the procedural requirements of NEPA (40 CFR parts 1500 to 1508). To comply with CEQ regulations, in the **Federal Register** of April 26, 1985 (50 FR 16636), FDA revised its NEPA policies and procedures (part 25 (21 CFR part 25)).

The CEQ regulations, which are binding on all Federal executive agencies, establish procedures for implementing NEPA. Agencies may adopt procedures to supplement CEQ's regulations. In adopting NEPA-implementing procedures, Federal Agencies are directed by CEQ to reduce paperwork (40 CFR 1500.4(p) and 1500.2(b)) by using several means, including the use of categorical exclusions. Under the CEQ regulations, agencies are required to review their policies and procedures and, in consultation with CEQ, revise them as necessary to ensure full compliance with the purpose and provisions of NEPA (40 CFR 1507.3).

CEQ defines categorical exclusions as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required (40 CFR 1508.4). When categorically excluding an action, an agency must determine that there are no extraordinary circumstances related to the action that may result in the action having significant environmental effects.

In the **Federal Register** of July 29, 1997 (62 FR 40570), FDA published final regulations governing compliance with NEPA as implemented by the CEQ regulations. The final rule listed certain device actions as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required.

II. Special Controls

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act (Public Law 107–250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three classes of devices that receive varying levels of regulation, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. Class II devices are those for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, post market surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

Prior to SMDA, the statutory definition of class II contemplated only the establishment of mandatory performance standards under section 514 of the act (21 U.S.C. 360d). The SMDA, however, broadened the definition of a class II device to provide options in addition to the establishment of a performance standard. Consistent with the pre-SMDA definition of a class II device, FDA had categorically excluded issuance, amendment, or repeal of a standard for a class II device (§ 25.34(c)). Because the agency may now establish special controls that include options in addition to mandatory performance standards, FDA is proposing to amend its environmental impact regulation under § 25.34 to expand the existing categorical exclusions. FDA proposes to include issue, amendment, or repeal of a rule related to the establishment of any special control, if it will not result in an increase in the existing levels of use or changes in the intended use of a device or its substitutes.

Generally, FDA issues special controls in order to assure that class II devices provide a reasonable assurance of safety and effectiveness. The categorical exclusion does not apply if the action will result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes. Under these conditions, FDA believes that it is appropriate to categorically exclude the establishment of a special control from the requirement to prepare an EA or EIS.

III. Humanitarian Device Exemption

The SMDA added section 520(m) to the act (21 U.S.C. 360j(m)) to encourage the development of devices intended for use in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States (humanitarian use devices). Accordingly, section 520(m) of the act authorizes FDA to exempt humanitarian use devices from the ''effectiveness requirements'' of sections 514 and 515 of the act (21 U.S.C. 360e) (i.e., ''reasonable assurance that the device is effective''). FDA may grant such an exemption provided that the following occurs: (1) The device is designed to treat or diagnose a disease or condition that affects fewer that 4,000 individuals in the United States; (2) the device would not be available to a person with such disease or condition unless the exemption is granted; (3) no comparable device (other than the device that has been granted such an exemption) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from

using the device outweighs the risk of injury or illness from its use, taking into account the probable risk and benefits of currently available devices or alternative forms of treatment.

There are two steps to obtaining approval of a humanitarian use device. First, the applicant must submit a request for humanitarian use device designation to FDA's Office of Orphan Products Development (§ 814.100(c)(1) (21 CFR 814.100(c)(1))). Next, the applicant must submit an HDE application (§ 814.100(c)(2)). Approval of an HDE authorizes marketing of the device. Designation of a device as a humanitarian use device is not a ''major federal action'' subject to analysis under NEPA because it is a determination that a device is eligible to apply for HDE approval and is not a final determination that any particular device may be marketed. A determination that a device is eligible to apply for HDE approval cannot by itself affect the environment. (*See Alliance for Bio-Integrity* v. *Shalala*, 116 F. Supp. 2d 166, 174 (D.D.C. 2000)).

FDA is proposing to amend § 25.34 to include approval of an HDE as a category of action that does not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor EIS is required. Because humanitarian use devices are limited by definition to use for treating or diagnosing diseases or conditions affecting fewer than 4,000 individuals in the United States per year, any environmental impact associated with use of a humanitarian use device is very limited. Additionally, FDA approves few HDEs (34 over the 7 years the program has been in effect), further limiting any potential environmental impact. Finally, FDA's experience in reviewing HDEs has shown that no HDE reviewed thus far has had a significant environmental impact.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an EIS is required.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule provides for an exclusion from the requirement to prepare an EA or EIS and, as such, relieves a burden, the agency certifies that the proposed rule will not have significant impact on substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $110 million. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Paperwork Reduction Act of 1995

This proposed rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

List of Subjects

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of the Food and Drug Administration, it is proposed that 21 CFR part 25 be amended as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

2. Section 25.34 is amended by revising paragraph (b) and adding paragraph (i) to read as follows:

§ 25.34 Devices and electronic products.

* * * * *

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

* * * * *

(i) Approval of a humanitarian device exemption under subchapter H of part 814 of this chapter.

Dated: November 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25974 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–138176–02]

RIN 1545–BA99

Timely Mailing Treated as Timely Filing; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: This document contains a notice of public hearing on proposed regulations that would amend § 301.7502–1(e) to provide that, other than direct proof of actual delivery, a registered or certified mail receipt is the only prima facie evidence of delivery of documents that have a filing deadline prescribed by the internal revenue laws.

DATES: The public hearing will be held on Tuesday, January 11, 2005, at 10 a.m. Outlines of topics to be discussed at the hearing must be received by December 28, 2004.

ADDRESSES: The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Send submissions to CC:PA:LPD:PR (REG–138176–02), room 5203, Internal Revenue Service, POB, 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m.

to CC:PA:LPD:PR (REG–138176–02), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at *http://www.irs.gov/regs.* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–138176–02).

FOR FURTHER INFORMATION CONTACT: Concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing Sonya M. Cruse, (202) 622–4693 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking (REG–138176–02) that was published in the **Federal Register** on September 21, 2004 (69 FR 56377).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who have submitted written comments and wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (signed original and eight (8) copies) by December 28, 2004.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing. Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures and Administration).

[FR Doc. 04–26063 Filed 11–23–04; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–023]

RIN 1218–AC08

Updating OSHA Standards Based on National Consensus Standards

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Proposed rule; notice of project to update OSHA standards that are based on National Consensus Standards.

SUMMARY: OSHA is engaging in an overall effort to update OSHA standards that reference, or that include language taken directly from, outdated consensus standards. The Agency adopted many of these standards over 30 years ago under Section 6(a) of the Occupational Safety and Health Act of 1970. Most of the referenced documents have been either superseded by later versions or withdrawn by the issuing Standards Development Organization (SDO). Many are no longer in print or available to the public through the issuing SDO. The outdated versions in the OSHA standards do not reflect advances in technologies that have changed workplace safety over the last 30 years. OSHA will use a variety of regulatory approaches to update these standards, including notice and comment rulemaking, direct final rulemaking, and technical amendments.

DATES: Comments to this notice must be submitted by the following dates:

- *Hard copy:* Your comments must be submitted (postmarked or sent) by December 27, 2004.
- *Electronic transmission and facsimile:* Your comments must be sent by December 27, 2004.

ADDRESSES: You may submit written comments on this notice—identified by docket number S–023 or RIN number 1218–AC08—by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *OSHA Web Site: http://ecomments.osha.gov.* Follow the instructions for submitting comments on OSHA's Web page.
- *Fax:* If your written comments are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648.
- *Regular mail, express delivery, hand delivery, and courier service:* Submit three copies to the OSHA Docket Office, Docket No. S–023, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–2625, Washington, DC 20210; telephone (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) OSHA Docket Office hours of operation are 8:15 a.m. to 4:45 p.m., EST.

Instructions: All comments received will be posted without change to *http://dockets.osha.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://dockets.osha.gov.*

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries contact George Shaw, Acting Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999. For technical inquiries, contact Ted Twardowski, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2070 or fax (202) 693–1663. Copies of this **Federal Register** notice are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1888. Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

OSHA has used consensus standards extensively as a basis for its mandatory safety and health standards since the earliest days of the Occupational Safety and Health Act of 1970 (OSH Act), 29 U.S.C. 651 *et seq.* Under Section 6(a) of the OSH Act, OSHA was given the authority for a period of 2 years to adopt both national consensus standards and established Federal standards as OSHA standards without following notice and comment rulemaking procedures. 29 U.S.C 655(a). Congress provided this authority so that OSHA would have a mechanism to begin immediately protecting the Nation's workers through mandatory standards. Using Section 6(a), the Agency adopted many consensus standards as OSHA standards.[1] OSHA adopted some of the

[1] OSHA also adopted under Section 6(a) a number of industry standards that were established Federal Standards or that were referenced in national consensus standards. For convenience only, this

Continued

consensus standards through ''incorporation by reference.'' When it incorporates a consensus standard by reference, OSHA requires employers to follow a consensus standard—identified by name and date in the Code of Federal Regulations—made available for inspection at the Office of the Federal Register, the OSHA Docket Office, and OSHA's Regional Offices. *See* 29 CFR 1910.6. OSHA adopted other consensus standards by importing relevant language from them directly into the regulatory text of OSHA standards.

Under Section 6(b) of the OSH Act, which authorizes OSHA to promulgate safety and health standards through notice and comment rulemaking, OSHA has since promulgated a number of rules that reference, or are based in large measure on, consensus standards. Some of these Section 6(b) rulemakings involved updating OSHA standards that were originally adopted from consensus standards under Section 6(a), as discussed above.

Today, there are about 200 consensus standards referenced throughout the OSHA standards for general industry and maritime. The references appear in hundreds of requirements and range from informational references to mandatory requirements.

While OSHA has updated some of its Section 6(a) standards through notice and comment rulemaking, the vast majority have not been updated since they were originally adopted. Some of the consensus standards ''incorporated by reference'' were issued over 60 years ago. Most of the referenced consensus documents have been either superseded by later versions or withdrawn by the issuing Standards Development Organization (SDO). Many are no longer in print or available to the public through the issuing SDO. These outdated standards do not reflect advances in technologies that have changed workplace safety over the last 30 years. The OSHA versions also have not been updated to address new equipment and machinery that have become available since they were originally promulgated.

OSHA has a policy of issuing ''de minimis'' notices to employers who comply with more current versions of consensus standards, to the extent that the more current versions are at least as protective as the older versions. *See* OSHA Instruction CPL 2.45B, p. IV–31. The ''de minimis'' policy does not address all of the difficulties for employers, employees, and OSHA enforcement personnel created by OSHA referencing outdated consensus standards. For example, referencing outdated consensus standards adds time-consuming administrative burdens on employers seeking to comply with OSHA standards. Employers need to research the referenced consensus standards, identify and analyze any updates to the standards, and determine how they apply to their workplaces. This task is made more difficult because many of the referenced consensus standards are no longer available through the issuing SDOs. Referencing outdated consensus standards also places heavy administrative burdens on OSHA. In applying the ''de minimis'' policy, OSHA must currently analyze later versions of the referenced consensus standards, and determine whether they are as protective as the referenced versions. OSHA believes that it would be far more productive for the Agency to use its time and resources to update its standards to reflect advances in consensus standard development and to address more effectively the new technologies and equipment that are found in today's workplaces.

II. Consensus Standards Update Project

OSHA recognizes the value of consensus standards and the widespread preference for OSHA rules to reflect the latest versions of these standards. SDOs rely upon the expertise of individuals with diverse backgrounds to produce consensus standards that consider the latest developments in workplace safety. As mentioned above, Congress placed such a high value on national consensus standards that it authorized the Agency to adopt them as OSHA standards, without notice and comment rulemaking, during the first two years of the OSH Act under Section 6(a). In addition, Section 6(b)(8) of the OSH Act states: ''Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the **Federal Register** a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.'' 29 U.S.C. 655(b)(8).

In the National Technology Transfer and Advancement Act (NTTAA), 15 U.S.C. 272, Congress directed Federal agencies to use voluntary consensus standards ''to the extent practicable'' and to participate in the development of voluntary consensus standards. The Office of Management and Budget has issued Circular A–119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* to guide agencies in implementing the NTTAA. While the NTTAA does not expand the obligations OSHA already has under Section 6(b)(8) of the OSH Act (to consider consensus standards during rulemaking), it demonstrates the importance Congress continues to place on the use of consensus standards by administrative agencies.

Consensus standards often attempt to reconcile diverse global standards and eliminate barriers to trade by finding areas of agreement on the safety aspects of machinery and equipment. In addition, Federal agencies can make use of the expertise of the developers of these standards and participate with them in the development process.

Recognizing the importance of consensus standards, and the difficulties presented by OSHA's continued reliance on outdated consensus standards, we are beginning an effort to (1) update or revoke outdated consensus standards referenced in OSHA standards, and (2) update standards that incorporate language directly from outdated consensus standards. OSHA anticipates that this will be an extended and ongoing process. The OSH Act does not provide a quick way to update mandatory safety and health standards. OSHA is not able to adopt the latest versions of national consensus standards without notice and comment, as it was authorized to do for 2 years under Section 6(a). Instead, OSHA must conduct rulemaking under Section 6(b) to accomplish this task.

OSHA has previously solicited information and suggestions from the American National Standards Institute (ANSI) and other SDOs on how to proceed with this project. *See* Ex. 2–1, Letter from OSHA to ANSI and SDOs dated April 23, 2002. OSHA explained in that solicitation that the references to outdated consensus standards created difficulties for employers in a number of respects. OSHA noted that many of the outdated versions are no longer available from the issuing SDO and that there are often questions about the degree of protection and the lack of currency with technological developments in various areas. OSHA specifically asked SDOs to identify which referenced standards had been updated by the SDOs since their adoption by OSHA, and to provide input on the following questions:

- Whether material changes have been made to the referenced consensus standards so that the current versions are substantially different from the versions in the CFR;

notice also refers to such standards promulgated under Section 6(a) as ''consensus standards.''

• Whether the adoption of the current versions would be controversial; and

• Whether the latest versions reduce risk more than the versions that are currently incorporated in OSHA standards.

Various SDOs and other organizations responded and indicated their desire to assist OSHA in its effort to update its standards. Among the SDOs providing input were ANSI, the National Fire Protection Association (NFPA), the American Society of Mechanical Engineers (ASME), and the American Society for Testing and Materials. Other organizations such as Underwriters Laboratories, the American Petroleum Institute, the Compressed Gas Association, and the Abrasive Wheel Institute also responded. Many of the SDOs and other organizations provided OSHA with copies of the most recent versions of their referenced standard(s) and offered to provide technical assistance to the Agency in its analysis of the older and new standards. OSHA appreciates the willingness of these organizations to help us implement this project.

Nearly all of the SDOs said that OSHA's standards needed updating to reflect current versions of the consensus standards and that the current versions provided a higher level of safety to workers. In addition, many of the SDOs believe that OSHA's efforts to update its standards to reflect current versions of the consensus standards will not elicit controversy. For example, the ASME said:

> [We] believe that adoption of the current version of each of these standards by the Federal Government with the changes identified would be non-controversial. Similarly, it is our opinion that the current versions of ASME standards will provide a reduction in the risk of accidents and injuries as compared to earlier versions presently referenced in the CFR and will alleviate some of the confusion in the regulated industry. Moreover, in addition to the technological advances incorporated into updated standards, many of the products described in the older versions of standards are no longer available, or are very difficult to obtain. Ex. 2–2, p. 2.

The NFPA noted that each of their documents has been updated ''to reflect up-to-date terminology and current industry practices.'' Ex. 2–3, App. B. The updated documents often cover technology that has been developed since the OSHA standard was promulgated. ''Providing a state-of-the-art document reflecting business practices of today promotes more of an understanding, appreciation and the much-necessary buy-in by the users of the regulations, thereby reducing risk.'' Ex. 2–3, App. B.

The NFPA also thought the updated references ''would be largely non-controversial since the documents are ANSI consensus standards.'' Ex. 2–3, App. B. In addition, the NFPA said that ''[w]ith the interested parties participating in the process to write documents, and with the respective affected industries and their insurance companies currently using NFPA documents, there is little controversy with OSHA referencing the most updated NFPA codes and standards.'' Ex. 2–3, App. B. The NFPA also said that for those OSHA standards that contain word-for-word text from NFPA codes and standards, OSHA should consider replacing the text ''with a simple reference to the applicable primary NFPA document.'' Ex. 2–3, App. B.

OSHA is undertaking a series of regulatory projects to update its standards to reflect the current versions of consensus standards. These regulatory projects will include updating or revoking outdated consensus standards incorporated by reference, and updating regulatory text of current OSHA rules that were adopted directly from the language of outdated consensus standards. OSHA will use a variety of regulatory approaches in this effort, including:

1. *Notice and comment rulemaking.* OSHA intends to initiate formal (notice and comment) rulemaking to update or revoke references to outdated consensus standards in instances where OSHA anticipates that the action would either impose compliance costs or raise significant issues. OSHA will also use traditional notice and comment rulemaking to update OSHA provisions that were derived directly from the text of outdated consensus standards. OSHA is already using this technique to update its electrical installation standards in Subpart S of Part 1910 (proposed rule published April 5, 2004, 69 FR 17774) and expects to publish a proposed rule in the near future for Subpart V (power transmission and distribution lines and equipment) of Part 1926.

2. *Direct final rulemaking.* OSHA will use direct final rulemaking to update or revoke, as appropriate, references to outdated consensus standards where the regulatory change is non-controversial, equally protective, and does not impose significant new compliance costs.

3. *Technical amendments.* Where appropriate, OSHA intends to issue technical amendments to update references that are currently incorporated into OSHA standards and that only provide information to the regulated community. Such references impose no compliance obligations and can be updated without notice and comment procedures.

OSHA welcomes comments on this update effort generally, as well as specific suggestions on which projects OSHA should pursue first.

Authority and Signature

This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order 5–2002 (67 FR 65008), and 29 CFR part 1911.

Signed at Washington, DC, this 17 day of November 2004.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 04–26047 Filed 11–23–04; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA–124–FOR]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening of public comment period.

SUMMARY: We are reopening the public comment period on a proposed amendment to the Pennsylvania regulatory program (the ''Pennsylvania program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Since the close of the comment period, Pennsylvania has provided explanatory information in response to two letters, as amended, we sent requesting clarification with regard to its proposed amendment. Pennsylvania has also withdrawn portions of its original amendment and has requested that we consider some existing statutes and regulatory provisions as part of the amendment. Pennsylvania has also indicated its intent to further revise portions of the amendment. We are accepting comments on the specific changes noted below only.

DATES: We will accept written comments on this proposal until 4 p.m., (local time) December 9, 2004.

ADDRESSES: You may submit comments, identified by PA–124–FOR, by any of the following methods:

- E-mail: *grieger@osmre.gov*. Include PA–124–FOR in the subject line of the message.
- Mail/Hand Delivery: George Rieger, Director, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, Harrisburg Transportation Center, Third Floor, Suite 3C, 4th and Market Streets, Harrisburg, Pennsylvania 17101.
- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Pennsylvania program, this amendment, and all written comments received in response to this document at the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Pittsburgh Field Division.

George Rieger, Director, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, Harrisburg Transportation Center, Third Floor, Suite 3C, 4th and Market Streets, Harrisburg, Pennsylvania 17101, E-mail: *grieger@osmre.gov*, Telephone: (717) 782–4036.

Joseph P. Pizarchik, Director, Bureau of Mining and Reclamation, Pennsylvania Department of Environmental Protection, Rachel Carson State Office Building, PO Box 8461, Harrisburg, Pennsylvania 17105–8461, Telephone: (717) 787–5103.

FOR FURTHER INFORMATION CONTACT: George Rieger, Telephone: (717) 782–4036, E-mail: *grieger@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program
II. Description of the Proposed Action
III. Public Comment Procedures

I. Background on the Pennsylvania Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Pennsylvania program in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning the Pennsylvania program and program amendments at 30 CFR 938.11, 938.12, 938.15 and 938.16.

II. Description of the Proposed Action

By letter dated December 18, 1998 (Administrative Record No. PA 853.01), the Pennsylvania Department of Environmental Protection (PADEP) submitted a proposed amendment to its program pursuant to various issues including bonding, remining and reclamation, postmining discharges, and water supply protection/replacement. The proposal included two documents: ''Provisions of Pennsylvania's Statute—Surface Mining Conservation and Reclamation Act—Submitted for Program Amendment'' and ''Provisions of Pennsylvania's Regulations—25 Pa. Code Chapters 86–90—Submitted for Program Amendment.''

We announced receipt of the proposed amendment in the March 12, 1999, **Federal Register** (64 FR 12269), and in the same document invited public comment and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on April 12, 1999. Please refer to the March 12, 1999, **Federal Register** for additional background information. In the July 8, 1999, **Federal Register** (64 FR 36828), we reopened the comment period in response to a June 1, 1999, letter (Administrative Record No. PA 853.11) from PADEP regarding deletion of the definition of the term ''best professional judgment'' at 25 Pa. Code 87.202 and 25 Pa. Code 88.502, and the deletion of subsections 25 Pa. Code 87.207(b) and 25 Pa. Code 88.507(b). The reopened comment period closed on July 23, 1999.

By letters dated September 22, 1999 (Administrative Record No. PA 853.14), and April 6, 2000 (Administrative Record No. PA 853.17), we requested clarification from Pennsylvania on various aspects of its amendment. In an October 3, 2002, letter to Pennsylvania (Administrative Record No. PA 853.22), we indicated that some of the issues in our September 22, 1999, and April 6, 2000, letters were no longer valid and that we were withdrawing our request for clarification of those issues. The conclusions in this letter were the result of our internal deliberations; we did not remove our request for clarification of these issues as the result of information from any other source. Since the issuance of the October 3, 2002, letter, we have had numerous meetings with Pennsylvania to discuss the items remaining from the September 22, 1999, and the April 6, 2000, letters.

The meetings with Pennsylvania resulted in Pennsylvania providing information to us to clarify the meaning of various parts of its amendment. We prepared a document listing those clarifications and placed it in the administrative record (Administrative Record No. PA 853.25). Copies of that document can be obtained from OSM's Harrisburg Office at the address noted above. The parts of Pennsylvania Surface Mining Conservation and Reclamation Act (PASMCRA) that we received clarifications on include: Sections 4(d); 4(d)(2); 4(g)(1) and (3); 4.2(f)(2) and (3); 4.13; 18(a.1); and 18.9. We received clarifications from Pennsylvania on the following regulations at 25 Pa. Code Chapter 86: Sections 86.151(c); 86.158(e) and (f); 86.168; 86.174(a); 86.252 (definition of ''remining area''); 86.253(b)(2)–(4); and 86.354. Finally, we received clarifications from Pennsylvania on the following portions of 25 Pa. Code Chapter 87: 87.119(d) and (e). We are seeking comment on the clarifications PADEP provided to us of these sections.

Additionally, Pennsylvania submitted two letters to us modifying the December 18, 1998, amendment. Those letters were dated December 23, 2003 (Administrative Record No. PA 853.23), and April 13, 2004 (Administrative Record No. PA 853.24).

In the December 23, 2003, letter, Pennsylvania noted that in the 1998 amendment submission it had proposed the removal of certain language in 25 Pa. Code Chapters 87–90 including: Sections 87.102; 87.103; 87.207(b); 88.92; 88.93; 88.187; 88.188; 88.292; 88.293; 88.507(b); 89.52; 89.53; 90.102; and 90.103 which provide effluent limits for discharges from areas disturbed by coal mining activities. In the 1998 amendment, Pennsylvania also requested the definition of the phrase, ''dry weather flow'' in 25 Pa. Code 87.1, 88.1, 89.5, and 90.1 and the definition of the phrase, ''best professional judgment'' in Sections 87.202 and

88.502 be removed from the approved program. In the December 23, 2003, letter, Pennsylvania revised the 1998 amendment as submitted to retain, as part of its approved program, the above referenced regulations which provide effluent limits and the definitions of ''dry weather flow'' and ''best professional judgment.'' Therefore, we consider those portions of the 1998 amendment submission as withdrawn and they will not be considered further in this rulemaking. No comments will be accepted with regard to these areas.

Also in the December 23, 2003, letter Pennsylvania indicated that the 1998 program amendment had included Sections 4(g.1), 4(g.2), and 4(g.3) of PASMCRA relating to minimal impact postmining discharges and the release of bonds on mine sites with discharges. Pennsylvania noted in that letter that since the definition of minimal impact postmining discharges and the regulations for postmining discharges were not included in the program amendment, it was requesting that these sections of PASMCRA be removed from the proposed amendment. Pennsylvania noted in the letter that it was intending to submit these sections along with the associated regulations as a separate program amendment. Therefore, these sections are also withdrawn and will not be considered further in this rulemaking. No comments will be accepted with regard to these areas.

In the April 13, 2004, letter, Pennsylvania notified us that it wished to withdraw Section 18(a.4) of PASMCRA from consideration under the 1998 program amendment because the areas suitable for reclamation by remining program has not yet been developed. Therefore, this section will not be considered further in this rulemaking. No comments will be accepted with regard to these areas.

Also in its April 13, 2004, letter Pennsylvania requested that we consider for approval Sections 4.10 and 4.11 of PASMCRA and the corresponding regulations at 25 Pa. Code Sections 86.251 through 86.270. These sections of the statute and regulations provide for Pennsylvania's Remining Operators Assistance Program. This program provides incentives to operators to undertake reclamation and remining of abandoned mine lands and bond forfeiture sites. These provisions are now included in this rulemaking action and we are seeking comment with regard to these sections of PASMCRA and 25 Pa. Code Chapter 86.

In the April 13, 2004, letter, and its attachment, Pennsylvania also notified us that it intends to address outstanding issues in this amendment relating to: *De minimis* cost increases for a replacement water supply; temporary replacement of water supply; waivers for water supply replacement; adequate versus equivalent water supply; operation and maintenance costs for replaced water supplies; financial guarantees to operators to reclaim abandoned mine lands through remining; and, operator cost recovery, through additional regulation changes. While Pennsylvania has indicated that it intends to further revise those portions of the pending package, it has not withdrawn those portions and has asked that we proceed with a decision. Since we received no changes or clarifications from the original amendment with regard to these areas, we are not reopening the comment period for them.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the information described above satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Written Comments

Send your written or electronic comments to OSM at the address given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We will not necessarily consider or respond to your comments when developing the final rule if they are received after the close of the comment period (*see* **DATES**). We will make every attempt to log all comments into the administrative record, but comments delivered to an address other than the Harrisburg Office may not be logged in.

Electronic Comments

Please submit Internet comments as an ASCII or Word file avoiding the use of special characters and any form of encryption. Please also include ''Attn: SATS No. PA–124–FOR'' and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Harrisburg Office at (717) 782–4036.

Availability of Comments

We will make comments, including names and addresses of respondents, available for public review during normal business hours. We will not consider anonymous comments. If individual respondents request confidentiality, we will honor their request to the extent allowable by law. Individual respondents who wish to withhold their name or address from public review, except for the city or town, must state this prominently at the beginning of their comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public review in their entirety.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 9, 2004.

Brent Wahlquist,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 04–25971 Filed 11–23–04; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0142; FRL–7686–4]

Trifluralin; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish a tolerance for residues of trifluralin in mint oil under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The amendment substantially rewrote section 408 of FFDCA. As a result, the revisions made it necessary, once again, to establish tolerances on certain commodities, such as mint oils, that had previously been deemed unnecessary.

DATES: Comments must be received on or before January 24, 2005.

ADDRESSES: Submit your comments, identified by docket identification (ID) number OPP–2004–0142, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *Agency Website*: *http://www.epa.gov/edocket/*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- *E-mail*: Comments may be sent by e-mail to *opp-docket@epa.gov*,

Attention: Docket ID Number OPP–2004–0142.

- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0142.
- *Hand Delivery*: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0142. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number OPP–2004–0142. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL–7181–7).

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8195; e-mail address: *pates.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a professional applicator, commercial applicator, residential applicator, agricultural worker, and/or a non-residential user. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov, or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background and Statutory Findings

EPA on its own initiative, under section 408(e) of FFDCA, 21 U.S.C. 346a(e), is proposing to establish a permanent tolerance for residues of the herbicide trifluralin in mint oil at 2.0 parts per million (ppm).

Tolerances under section 408 of FFDCA for trifluralin in or on peppermint tops and spearmint tops are established in 40 CFR 180.207 at 0.05 ppm. Previously, under section 409 of FFDCA, tolerances were established for trifluralin in peppermint oil and spearmint oil at 2.0 ppm. In 1996, these section 409 of FFDCA tolerance regulations were revoked as unnecessary. Shortly thereafter, the FFDCA was amended by FQPA. This amendment substantially rewrote section 408 of FFDCA and consolidated, for the most part, the authority addressing pesticide residues in food under section 408 of FFDCA. The revisions to section 408 of FFDCA also made it necessary, once again, to establish tolerances on certain commodities, such as mint oils, that had previously been deemed unnecessary.

The Agency has completed the human health risk assessment for trifluralin and is now proposing to establish a permanent tolerance at 2.0 ppm for mint oil. Also, all existing tolerances are being maintained at current levels and are considered to be reassessed by the Trifluralin Tolerance Reassessment Eligibility Decision (TRED) signed on August 31, 2004.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of trifluralin in mint oil at 2.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows:

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by trifluralin are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.3100 2-Week R-F Feeding—Rats (male)	00157154 (1983) 0; 6,500 ppm range-finding study for 00157156 (1985), 41038301 (1986) Acceptable/Nonguideline	NOAEL = Not achieved LOAEL = 6,500 ppm based on renal epithelial damage, urine triple phosphates crystals and urinary sediment
870.3100 90-Day Oral toxicity—Rat	00151906 (1980) 0; 800; 2,000; or 5,000 ppm M: 0, 59, 154, and 392 milligram/kilogram/day (mg/kg/day) F: 0, 69, 168, and 421 mg/kg/day Acceptable/Guideline	NOAEL = 2,000 ppm (154/168 mg/kg/day, Male/Female (M/F)) LOAEL = 5,000 (392/421(mg/kg/day), M/F) Based on minor decreases in overall body weight gains and food consumption in males and females, decreased hemoglobin, alkaline phosphatase, and alanine aminotransferase in the males, and increased absolute and relative (to body) liver weights in males and females
870.3200 21/28-Day dermal toxicity—Rabbit	41993810 (1991) 0, 100, 500, or 1,000 mg/kg/day (formulation containing 35.8% trifluralin and 2.6% XRD-498) Acceptable/Guideline	Systemic NOAEL =1,000 mg/kg/day Systemic LOAEL = Not achieved Dermal NOAEL = Not achieved Dermal LOAEL = 100 mg/kg/day, edema, and/or scaling and fissuring 100 mg/kg/day based skin irritation
870.3200 31-Day dermal toxicity—Rat	00153171 (1982) 0; 40; 200; or 1,000 mg/kg/day Acceptable/Guideline	Systemic NOAEL = 1,000 mg/kg/day (limit dose) Systemic LOAEL = Not achieved Dermal NOAEL = 40 mg/kg/day Dermal LOAEL = 200 mg/kg/day based on sub-epidermal inflamation and ulcerations inmales and females

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES—Continued

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.3200 21/28-Day dermal toxicity—Rat	00152888 (1985) 0; 1,000 mg/kg/day (limit dose) Acceptable/Guideline	Systemic NOAEL = 1,000 mg/kg/day Systemic LOAEL = Not achieved Dermal NOAEL= Not achieved Dermal LOAEL = 1,000 mg/kg/day (limit dose) based on erythema, edema, and desquamination of the treated skin
870.3465 30-Day inhalation toxicity	40392312 (1987) reformat of 00151904 (1982) 0; 100; 301; 1,006 mg/m^3(6 hours/day 5 days/week for up to 30 days) Acceptable/Nonguideline	NOAEL = 301 mg/m^3 LOAEL = 1,006 mg/m^3 based on increased bilirubin in females and incidences of dyspnea and ruffled fur in males and females
870.3700 Developmental Toxicity Study—Rat	00151899 (1983), 159620 (1986), 40392310 (1987) 0, 20, 100, 500 mg/kg/day	Systemic Maternal NOAEL = 100 mg/kg/day Systemic Maternal LOAEL = 500 mg/kg/day based on mortality, clinical signs, decreased body weight gains, decreased food consumption, and increased liver and spleen weights Developmental NOAEL =100 mg/kg/day Developmental LOAEL = 500 mg/kg/day based on reduced ossification of the vertebrae and ribs and thickened, wavy or bent ribs and increased incidences of resorptions
870.3700 Developmental Toxicity Study—Rat	00152419 (1984) 0; 100; 225; 470; or 1,000 mg/kg/day Acceptable/Guideline	Maternal NOAEL = 475 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decreased body weights and decreased food consumption Offspring NOAEL = 475 mg/kg/day Offspring LOAEL = 1,000 mg/kg/day based on decreased fetal body weights Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL was not established
870.3700 Developmental Toxicity—Rabbit	00152421 (1984) 0, 100, 225, 500 mg/kg/day Acceptable/Guideline	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 225 mg/kg/day based on abortions, macroscopic changes in the liver and lungs, and decreased food consumption Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 225 mg/kg based on abortions
870.3800 2-Generation reproduction—Rat	00151901 (1984) 00151902 (1984) Feed analysis 00151903 (1984) Path 0; 200; 650; 2,000 ppm 0, 20, 32.5, 200 mg/kg/day (1 ppm = 0.5 mg/kg/day) Acceptable/Guideline	Parental NOAEL = 200 ppm (10 mg/kg/day) Parental LOAEL = 650 ppm (32.5 mg/kg/day) based on mortality due to acute renal failure and increased lesions of the renal proximal tubules in the F1 females; increased relative (to body) weights of the liver, kidney (males), and testes in both generations Offspring NOAEL = 200 ppm (10 mg/kg/day) Offspring LOAEL = 650 ppm (32.5 mg/kg/day) based on decreased pup weights in both generations and increased relative to body liver weights in the F2b females Repro NOAEL = 2,000 ppm (100 mg/kg/day) Repro LOAEL = Not established
870.3800 2-Generation reproduction—Rat	00162543 (1986), 44135107 (1996) 0; 200; 630; 2,000 ppm 0, 15, 47, 148 mg/kg/day Acceptable/Guideline	Parental NOAEL = 200 ppn (15 mg/kg/day) Parental LOAEL = 630 ppm (47 mg/kg/day) based on decreased body weight gains (BWG) and food consumption Offspring NOAEL = 200 ppm (15 mg/kg/day) Offspring LOAEL = 630 ppm (47 mg/kg/day) based on small pup size in 3 litters Reproductive NOAEL = 2,000 ppm (148 mg/kg/day) Reproductive LOAEL = Not established
870.3800 2-Generation reproduction—Rat	40405007 (1987) 0; 50; 450; 4,000 ppm M: 0, 3.9, 35, 295 mg/kg/day F: 0, 4.7, 42, 337 mg/kg/day Acceptable/Guideline	Parental NOAEL = 450 ppm (35/42 mg/kg/day M/F) Parental LOAEL = 4,000 ppm (295/337 mg/kg/day M/F) based on decreased body weights, body weight gains, food consumption, and food efficiency in males and females of both generations; decreased ovary weights in both generations; colon distension in the F1 males; and uterine atrophy in the females of both generations Offspring NOAEL = 450 ppm (35/42 mg/kg/day M/F) Offspring LOAEL = 4,000 ppm (295/337mg/kg/day, M/F) based on decreased pup weight in F1a litters Reproductive NOAEL = 450 ppm (35/42 mg/kg/day) Reproductive LOAEL = 4,000 ppm(295/337 mg/kg/day M/F) based on decreased fetal, neonatal, and litter viability and decreased lactation index in the F1a pups; and decreased number of implantation sites, newborn pups, litter size, and pup weights in both generations

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES—Continued

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.4100 1-Year Oral (capsule) Study—Dog	00151908 (1984), 00159618 (1985) 0, 30, 150, or 750 ppm 0.0, 0.8, 3.8, 18.8 mg/kg /day Acceptable/Guideline	NOAEL = 30 ppm (0.8 mg/kg/day) LOAEL = 150 ppm (3.8 mg/kg/day) based on increased absolute liver weights in males
870.4100 1-Year Oral (capsule) Study—Dog	42447001 (1992) 0, 0.75, 2.4, 40 mg/kg/day Acceptable/Guideline	Systemic NOAEL = 2.4 mg/kg/day Systemic LOAEL = 40 mg/kg/day, based on increased frequency of abnormal stool and pigment deposition in the kidney and liver in males and females, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males
870.4300 24-Month Chronic Toxicity/Carcinogenicity Study—Rat	00162457 (1985), 00162458 (1985) 0; 200; 800; or 3,200 ppm M: 0, 10, 40, and 169 mg/kg/day F: 0, 13, 53, and 219 mg/kg/day Acceptable/Guideline	NOAEL = 800 ppm (40/53 mg/kg/day M/F) LOAEL = 3,200 ppm (169/219 mg/kg/day M/F) based on decreases in body weight and body weight gains At the doses tested, the carcinogenic potential of trifluralin was negative. Dosing was considered adequate based on differences in body weight and body weight gains.
870.4300 24- Month Carcinogenicity Study—Mouse	00158935 (1986), 40392313 (1987) 0, 50, 200, or 800 ppm M: 0, 7.5, 29, and 118 mg/kg/day F: 0, 10.5, 41, and 165 mg/kg/day Unacceptable/Guideline	Sys NOAEL = 800 ppm (118/165 mg/kg/day in males/females); highest dose tested System LOAEL = Not achieved NOAEL for the range finder was 2500 ppm (375 mg/kg/day), the highest dose tested
870.5100 Bacterial Reverse Gene Mutation Assay	MRID 00148345 (1984) Acceptable/Guideline	There was no evidence of induced mutant colonies over background.
870.5100 Bacterial Reverse Gene Mutation Assay	MRID 40334707 (1987) Acceptable/Guideline	There was no evidence of induced mutant colonies over background.
870.5100 Bacterial Reverse Gene Mutation Assay	MRID 00153173 (1979) Acceptable/Guideline	There was no evidence of induced mutant colonies over background.
870.5250 Gene Mutation Assay—Yeast	MRID 00151898 (1982) Acceptable/Guideline	There was no concentration-related positive response of induced mutant colonies over background.
870.5300 *In vitro* Mammalian Cell Gene Mutation Assay	MRID 00126661 Acceptable/Guideline	There was no concentration-related positive response of induced mutant colonies over background.
870.5450 Dominant Lethal—Rat	MRID 00148319 (1984) Acceptable/Guideline	There was no time-related positive response of increased pre- or post-implantation loss compared to controls.
870.5300 Forward Gene Mutation Assay	MRID 40765601 (1988) Acceptable/Guideline	There was no evidence of induced mutant colonies over background in the presence or absence of S9-activation.
870.5300 Forward Gene Mutation Assay	MRID 00148318 (1984) Acceptable/Guideline	There was no evidence of induced mutant colonies over background in the presence or absence of S9-activation.
870.5385 *In Vivo* Mammalian Cytogenetics (Bone Marrow/Spermatogonial Aberration Test)	MRID 40765603 (1988) Acceptable/Guideline	There was no evidence of chromosome aberration induced over background.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY TABLES—Continued

Guideline No./Study Type	MRID No. (year)/Classification/ Doses	Results/Comments
870.5385 *In Vivo* Mammalian Cytogenetics (Bone Marrow Chromosome Aberration Test)	MRID 00148320 Acceptable/Guideline	There was no evidence of chromosome aberration induced over background.
870.5395 *In Vivo* Mouse Erythrocyte Micronucleus Assay	MRID 00151895 (1981) Acceptable/Guideline	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow compared to controls.
870.5450 Dominant Lethal—Mouse	MRID 00151896 (1984) Acceptable/Guideline	There was no time-related positive response of increased pre- or post-implantation loss compared to controls.
870.5550 Unscheduled DNA synthesis in mammalian cell culture	MRID 40765602 (1988) Acceptable/Guideline	There was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts), was induced.
870.5550 Unscheduled DNA synthesis in mammalian cell culture	MRID 00151894 (1982) Acceptable/Guideline	There was no evidence that unscheduled DNA synthesis, as determined by liquid scintillation counting procedures, was induced.
870.5900 *In Vivo* Sister Chromatid Exchange Assay	MRID 00133426 (1983) Acceptable/Guideline	There was no evidence of SCE induced over background.
870.7845 Metabolism—Rat Urinary metabolites	41218901 (1989) Acceptable/Guideline	The objective of this study was to identify the urinary metabolites of trifluralin. There was no sex-dependent effect on metabolic profiles. A minimum of 20–30 non-conjugated metabolites and an additional 10–20 conjugated metabolites were present in the urine, but no parent compound was detected. Information on the percentage of the administered dose excreted in the urine was not provided. However, no single metabolite accounted for more than 8–10% of the total urinary radioactivity, and the majority of the metabolites were present at 1–2% of the total urinary radioactivity. Thus, almost all of the metabolites were minor (<5% of the total radioactive dose). Metabolite F1B was found at 8.2–8.9% of the total urinary radioactivity in both sexes, and Metabolite F2, N-[(3-(acetylamino)-2-amino-5-(trifluoromethyl)phenyl] acetamide, was found at 4.0–5.2%. Metabolite F1B was partially characterized as retaining the trifluoromethyl groups, the two equivalent aromatic protons, and the two nitro groups, but the propyl groups were lost. Ten other metabolites were identified (<0.1–3.7% of total urinary radioactivity, each compound in each sex). Two additional metabolites were partially characterized (0.–2.6% of total urinary radioactivity, each compound in each sex). Four metabolic pathways were identified as follows: i. Oxidative N-dealkylation of one or both propyl groups and metabolites which were hydroxylated on the propyl side chain. ii. Reduction of one or both nitro groups to the corresponding amine. iii. Cyclization reactions to give a variety of substituted and unsubstituted benzimidazole metabolites. iv. Conjugation reactions, including acetylation of the reduced nitro groups, sulfate, and glucuronic acid conjugates.
Special study 3-Month Feeding—Rat with Urinalysis Study	00157156 (1985), 40138301(1986), 41086101 (1989) 0; 50; 200; 800; 3,200; and 6,400 ppm 0, 2.6, 10.7, 42.2, 170.2, and 342.1 mg/kg/day Acceptable/Nonguideline.	NOAEL = 200 ppm (10.7 mg/kg/day) LOAEL for nephrotoxicity = 800 ppm (42.2mg/kg/day), based on the presence of cortical tubular cytoplasmic hyaline droplets; increased total protein, aspartate aminotransferase (AST), and lactate dehydrogenase (LDH) in the urine; and increased urinary volume upon protein electrophoresis and urinalysis. This study was to provide additional information to establish a NOAEL for nephrotoxicity, which was observed in a chronic feeding study in rats at the lowest dose tested.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory

animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. A UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such an additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach is a conservative method which assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Even though the Agency does not have a mouse study, the database is considered to be complete with the rat data. A summary of the toxicological endpoints for trifluralin used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLURALIN

Exposure scenario	Dose used in risk assessment, UF	Special FQPA SF* target MOE	Study and toxicological effects
Acute Dietary (Females 13–50 years of age)	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1.0 mg/kg/day	Special FQPA SF = 1 aPAD = 1.0 mg/kg/day	Developmental Toxicity Study—Rat LOAEL = 500 mg/kg/day based on increased total litter resorptions
Acute Dietary (General population, including infants and children)	No appropriate single dose endpoint was selected.		
Chronic Dietary All population	NOAEL = 2.4 mg/kg/day UF = 100 Chronic RfD = 0.024 mg/kg/day	Special FQPA SF = 1 cPAD = 0.024 mg/kg/day	Chronic Toxicity (capsule)—Dog LOAEL = 40 mg/kg/day based on based on increased frequency of abnormal stool, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males
Short-Term Incidental Oral (1–30 days)	NOAEL = 10 mg/kg/day	MOE = 100	2-Generation Reproduction Study—Rat LOAEL = 32.5 mg/kg/day based on decreased pup weights in both generations
Intermediate-Term Incidental Oral (1–6 months)	NOAEL = 10 mg/kg/day	MOE = 100	Special Urinalysis Study—Rat LOAEL = 40 mg/kg/day based on based on the presence of tubular cytoplasmic hyaline droplets; increased total protein, AST, and LDH in the urine; albumin α1-globulin and α2-globulin observed by urine electrophoresis; and increased urinary volume
Short-Term Dermal (1 to 30 days)	No quantification required since there was no systemic toxicity at the limit dose in the dermal toxicity study. There are no developmental toxicity concerns. The HIARC also recommends that the products containing trifluralin should be labeled as SENSITIZER.		
Intermediate-Term Dermal (1 to 6 months)	Oral study NOAEL = 10 mg/kg/day (dermal absorption rate = 3%)	Residential MOE = 100 Occupational MOE = 100	Special Urinalysis Study—Rat LOAEL = 40mg/kg/day based on based on the presence of tubular cytoplasmic hyaline droplets; increased total protein, AST, and LDH in the urine; albumin α1-globulin and α2-globulin observed by urine electrophoresis; and increased urinary volume
Long-Term Dermal (>6 months)	Oral study NOAEL = 2.4 mg/kg/day (dermal absorption rate = 3% when appropriate)	Residential MOE = 100 Occupational MOE = 100	Chronic Toxicity (capsule)—Dog LOAEL = 40mg/kg/day based on based on increased frequency of abnormal stool, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males

TABLE 2.—TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLURALIN—Continued

Exposure scenario	Dose used in risk assessment, UF	Special FQPA SF* target MOE	Study and toxicological effects
Short-Term Inhalation (1 to 30 days)	Inhalation study NOAEL= 81 mg/kg/day	Residential MOE = 100 Occupational MOE = 100	30-Day Inhalation Study—Rat LOAEL = 270 mg/kg/day based on increased methemoglobin and bilirubin in females and incidences of dyspnea and ruffled fur in males and females
Intermediate-Term Inhalation (1 to 6 months)	Oral study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	Residential MOE = 100 Occupational MOE = 100	Special Urinalysis Study—Rat LOAEL = 40 mg/kg/day based on based on the presence of tubular cytoplasmic hyaline droplets; increased total protein, AST, and LDH in the urine; albumin α1-globulin and α2-globulin observed by urine electrophoresis; and increased urinary volume
Long-Term Inhalation (>6 months)	Oral studyNOAEL= 2.4 mg/kg/day (inhalation absorption rate = 100%)	Residential MOE = 100 Occupational MOE = 100	Chronic Toxicity (capsule)—Dog LOAEL = 40 mg/kg/day based on based on increased frequency of abnormal stool, decreased body weights and body weight gains, and on decreased erythrocytes and hemoglobin and increased thrombocytes in males
Cancer (Oral, dermal, inhalation)	Q_1* = 5.8 X 10^{-3} $(mg/kg/day)^{-1}$. The Agency concluded that trifluralin is a ''Group C'' (limited evidence of carcinogenicity) carcinogen with a Q_1* of 0.0077 $(mg/kg/day)^{-1}$; (Based on male rat thyroid follicular cell tumors combined). Recalculation of the Q_1* with ¾s interspecies scaling factor resulted in a Q_1* of 0.00579 $(mg/kg/day)^{-1}$. (No additional data needed).		

UF = uncertainty factor, Special FQPA SF = Special FQPA safety factor - a FQPA safety factor based on concerns unique to the FQPA, NOAL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, NA = Not Applicable

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.207) for the residues of trifluralin, in or on a variety of raw agricultural commodities. Dietary exposure estimates are also factored by the estimated weighted average usage, or percent crop treated (PCT) data. Risk assessments were conducted by EPA to assess dietary exposures from trifluralin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Additionally, acute risks were also estimated using the Lifeline model (version 2.0). Lifeline converts the raw agricultural commodity (RAC) residues into food residues by randomly selecting a RAC residue value from the user defined residue distribution (created from the residue, PCT, and processing factors data), and calculating a net residue for that food based on the ingredient's mass contribution to that food item. The Lifeline model estimated acute exposure based on the acute 1-day dietary dose drawn randomly from an age-specific seasonal exposure profile of 1,000 individuals.

In the course of conducting a Tier 3 dietary exposure analysis, decisions are made regarding the following: The residue data used in the analysis (field trials, monitoring data, etc.) refinements incorporated in such as PCT and processing factors. Monitoring data were used for the majority of crops whereby field trial data was used for the remainder of the commodities. Monitoring data were translated to similar crops when possible, generally according to the Agency's Standard Operating Procedure (SOP) 99.3 ''Translation of Monitoring Data.'' The following commodities used USDA Pesticide Data Program (PDP) monitoring data: Carrots, celery, orange, peach, squash, sweet pepper, and wheat. For PCT, the following commodities noted 100 PCT: Apricot, apricot juice, apricots-dried, brussel sprouts, cherries, cherries-dried, cherries-juice, chicory, eggplant, endive (escarole), flax seed, horseradish, kohlrabi, mustard seeds, mung beans, oats, oats-bran, parsnip, rapeseed (canola oil), and salsify. However, the majority of PCT for all other commodities is well below 100% (e.g, mint = 3%). For a more comprehensive listing of all commodities regarding PCT see the Residue Chemistry Chapter for Trifluralin, which is provided as background in EPA's public docket at *http://www.epa.gov/edocket/* under docket ID number OPP–2004–0142.

An acute dietary assessment was not conducted for the general U.S. population or infants and children because there was no appropriate single dose endpoint for this population subgroup. Trifluralin is not acutely toxic and there is no expectation that single, or single-day high-end exposure, including aggregate exposure, will have an adverse effect.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 CSFII and accumulated exposure to the chemical for each commodity. The following summarizes the Agency's current method for determining exposure due to use on food commodities. Chronic dietary exposure is estimated for the general U.S. population and population subgroups defined by sex, age, region, and ethnicity. Durations of chronic

exposure vary from 1-year as represented by ''all infants,'' to lifetime exposure as represented by the general U.S. population, which combines all population subgroups to form a mean exposure value. It should be noted that all parameters of chronic dietary exposure estimates are averaged values (i.e., average food consumption, average residue, etc.). The assessment is based on PDP, field trial (provides an upper bound estimate of dietary exposure) and processing data. Dietary exposure estimates are also factored by the estimated weighted average usage, or ''percent crop treated'' data.

iii. *Cancer*. The estimated exposure of the general U.S. population (only) to trifluralin is 0.000028 mg/kg/day. Carcinogenic dietary risk is based on the chronic exposure estimate for the general U.S. population derived from the same residue, percent use, and averaged consumption data. Note that the consumption data for the general U.S. population represents all age groups, all geographic areas, all ethnic groups, and incorporates reports of no consumption (non-user). The final risk estimate is calculated by multiplying the average U.S. exposure estimate by the trifluralin upper-bound potency factor, or Q_1*.

iv. *Anticipated residue and percent crop treated (PCT) information*. The dietary assessment relies on field trial, monitoring (PDP), and usage data (PCT). Trifluralin residues were LOQ in/on all commodities except alfalfa, collards, flax seeds, and mint field trials.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual PCT for assessing chronic dietary risk only if the Agency can make the following findings:

Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Crops with less than 2.5 PCT: Alfalfa, almonds, apples, corn, grapes, lettuce, mint, onions, oranges, peaches, pears, pecans, prunes and plums, sorghum, and walnuts.

Crops with 5–20 PCT: Barley (5), broccoli (10), cantaloupes (15), cauliflower (10), celery (10), cucumbers (5), dry peas (15), honeydew (5), hops (5), lemons (5), okra (20), spring wheat (5), peanuts (10), potatoes (5), pumpkins (5), radishes (10), soybeans (15), spinach (10), squash (5), sugar beets (5), sugarcane (10), and watermelons (15).

Crops with 25 or more PCT: Asparagus (25), beans, green (35), cabbage (45), carrots (55), collards (35), cotton (45), dry beans (30), durum wheat (35), kale (25), greens, mustard (25), peas, green (30), peppers (25), safflower (60), sunflowers (30), tomatoes (50), and turnip (30).

Modeling was performed by using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) and Lifeline. Using the DEEM-FCID method, an estimate of the residue level in each food or food-form on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup. Using the same consumption data, Lifeline converts the Raw Agricultural Commodity an average daily exposure from a profile of 1,000 individuals over a 1-year period. In conjunction, a Screening Level Estimates of Agricultural Uses (SLUA) for trifluralin was used to estimate PCT. The SLUA provides a quick snap shot of pesticide use, by crop. For mint, the PCT of 3% was based on the SLUA report, which averages the total pounds applied to trifluralin and PCT from 1997–2001.

The Agency believes that the three conditions listed in this unit have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which trifluralin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient data to accurately determine dietary exposure from drinking water. Therefore, contamination estimates for drinking water are refined by PRZM-EXAMS modeling, incorporating percent cropped area (PCA) data.

Since trifluralin is registered on several crops, Tier II modeling crop scenarios were selected to reflect crops with the highest uses of trifluralin (soybeans and cotton), the maximum application rate (sugarcane), and availability of scenarios. The maximum daily peak concentration of trifluralin from PRZM/EXAMS simulation (38.1 parts per billion (ppb)) is greater than the highest concentration in the United States Geological Survey (USGS) National Water Quality Assessment (NAWQA) monitoring database (1.74 ppb) for surface water. However, the maximum annual average trifluralin concentration in surface water (1.9 ppb) is comparable to time weighted annual means (TWAM) concentrations in USGS monitoring studies (0.618 ppb). The minimum criteria for calculating TWAM concentration at a sampling station in a given year was a single detection of trifluralin. As to groundwater, the maximum trifluralin concentration predicted by SCI-GROW is 0.035 ppb and the maximum single value from NAWQA monitoring of ground water is 0.150 ppb. The 99.8 percentile NAWQA value is 0.012 ppb. Because these values are well below predicted and actual surface water values, no further analysis of the reliability of the maximum NAWQA groundwater value was conducted. Modeling was conducted using the maximum application rate for specific crops. Modeling estimates from typical application rates on specific crops will predict lower concentrations. For further information on trifluralin modeling and monitoring, see docket ID number OPP–2004–0142 at *http://www.epa.gov/edocket/* for the following documents: Trifluralin—Drinking Water Assessment for Tolerance Reassessment Eligibility Decision and a memorandum entitled Clarification of the Trifluralin Drinking Water Assessment for the Health Effects Division (HED) Tolerance Reassessment (PC Code: 036101) and characterization on relative differences of USGS NAWQA ground water monitoring data and its comparison to SCI-GROW model predictions as presented in the NRDC objection (see Imidacloprid in the **Federal Register** of May 26, 2004 (69 FR 30042) (FRL–7355–7)) and the trifluralin TRED.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

3. *Non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Trifluralin is currently registered for use on the following residential non-dietary sites: Home lawns, vegetable gardens, ornamental gardens (including planting beds, flowers, shrubs, and trees), including other residential sites such as golf courses, recreational parks, bike/golf cart paths, and cemeteries. The risk assessment was conducted using the following residential exposure assumptions:

- For residential scenarios, homeowner handlers are expected to complete all tasks associated with the use of a pesticide product, including mixing/loading as well as application.
- Residential handler exposure scenarios are only considered to be short-term in nature due to the episodic uses associated with homeowner products.
- Label use rates and use information specific to residential products serve as the basis for the risk calculations.
- Area/volumes of spray or chemical used in the risk assessment are based on Agency guidance specific to residential use patterns.

The Agency has determined that there are potential exposures to residential handlers (i.e., mixer, loader, applicators) during the usual use-patterns associated with trifluralin. Likewise, the Agency has determined that there are potential post-application exposures to adults and children in residential settings during the usual use-patterns associated with trifluralin. For non-cancer post-application risks, since there is no short-term dermal toxicological endpoint of concern for trifluralin and no intermediate-term dermal exposure is anticipated, the only assessment is for incidental ingestion by toddlers.

The Agency has also determined that there are potential post-application cancer risks for adults in residential areas treated with trifluralin. The following scenarios were assessed:

- Dermal exposure to residue on lawns.
- Dermal exposure to golf course turfgrass.
- Dermal exposure to residue on home gardens.

For the residential turfgrass scenario, the cancer risks were combined for residential handlers applying granular formulation to lawns with post-application cancer risks to adults from exercising on just-treated lawns. This combined two screening-level calculations.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to trifluralin and any other substances and does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There are no residual uncertainties for pre- and/or postnatal toxicity.

3. *Conclusion*. There is a complete toxicity database for trifluralin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on this information and the lack of any residual concerns for pre- and/or postnatal toxicity, EPA concludes it has

reliable data to remove the additional 10X FQPA safety factor.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

Aggregate exposure assessment is based, in part, on the assumption that there is a predictable level of chronic pesticide exposure, attributable to food and drinking water, and this level is estimated on a per day basis (mg/kg/day) by using averaged estimates of residue, use, and consumption. This average, or ''background'' level of exposure is assumed to be constant, not seasonal, and residential or other exposures are additive to this background.

For trifluralin, homeowner use is highly seasonal (mostly early Spring) and this exposure will likely be acute (one day of golf) or short-term (multiple residential applications). The route of exposure may be oral (children on turf), dermal (at application or post-application), or by inhalation (at application).

1. *Acute risk*. A quantitative acute dietary assessment was not conducted for the general U.S. population or population subgroups other than females 13–49 because there was no appropriate single dose endpoint. Exposure to trifluralin is not expected to pose an acute risk to these population groups. The upper-bound acute risk estimate for females 13–49 years of age is less than 1% of the aPAD at the 99.9th exposure percentile. Results of the Lifeline analysis (see Table 3 of this unit) are fully consistent with DEEM-FCID results (<1% aPAD).

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLURALIN (FOOD/ WATER COMBINED)

Acute Dietary Estimates (99.9th Percentile of Exposure)					
Population subgroup	PAD, mg/kg/day	DEEM-FCID		Lifeline	
		Exposure, mg/kg/day	% PAD	Exposure, mg/kg/day	%PAD
Females 13–49 years	1	0.000262	0.03	0.000311	<1

2. *Chronic risk*. Dietary risk for trifluralin is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the trifluralin cPAD, with dietary risk expressed as a percent of the cPAD. The cPAD is the chronic population adjusted dose; the chronic reference dose (0.024 mg/kg/day) modified by the FQPA safety factor. The trifluralin cPAD is 0.024 mg/kg/day based on a RfD of 0.024 mg/kg/day (see section 3.3.1, Endpoint Selection Discussion in the Trifluralin: Human Risk Assessment document), and incorporating the FQPA safety factor of 1X (no additional factor) for the overall U.S. population or any population subgroups.

The cPAD method of risk assessment is applicable to the oral exposure route and is used to assess both food and drinking water exposure. Exposure estimates that are less than 100% of the cPAD indicate a determination of safety can be concluded (see Table 4 of this unit).

TABLE 4.—CHRONIC DIETARY EXPOSURE AND RISK ESTIMATES

Chronic PAD Dietary Estimates					
Population subgroup	PAD, mg/kg/day	DEEM-FCID		Lifeline	
		Exposure, mg/kg/day	%PAD	Exposure, mg/kg/day	%PAD
U.S. Population	0.024	0.000030	<1	0.000019	<1
All infants (< 1 year)	0.024	0.000062	<1	0.000033	<1

TABLE 4.—CHRONIC DIETARY EXPOSURE AND RISK ESTIMATES—Continued

Chronic PAD Dietary Estimates					
Population subgroup	PAD, mg/kg/day	DEEM-FCID		Lifeline	
		Exposure, mg/kg/day	%PAD	Exposure, mg/kg/day	%PAD
Children 1–2 years	0.024	0.000073	<1	0.000051	<1
Children 3–5 years	0.024	0.000062	<1	0.000039	<1
Children 6–12 years	0.024	0.000041	<1	0.000024	<1
Youth 13–19 years and All Adults	0.024	0.000025	<1	0.000016	<1

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Dietary exposure is assumed to be constant, not seasonal and residential or other exposures are additive to this background. Homeowner use for trifluralin is highly seasonal and this exposure will likely be acute or short-term. Thus, the route of exposure may be oral (children on turf), dermal, or inhalation where residential exposure could occur with the use of trifluralin. However, no toxicological effects have been identified for short-term toxicity. Therefore, the aggregate risk does not exceed the Agency's level of concern.

The chronic dietary exposure and risk estimates for the general United States and population subgroups, are aggregate estimates based on both food and drinking water sources. The aggregate (3 specific exposure scenarios) incidental-oral exposure estimate for children on turf is 0.00009 mg/kg/day. When combined with the estimated chronic dietary exposure (0.000051 mg/kg/day) for children 1–2 years old, the sum is 0.00014 mg/kg/day. Compared to the appropriate dose (10 mg/kg/day) for short-term incidental-oral risk assessment, this aggregate exposure estimate is much greater than the target MOE of 100, and a conclusion of safety can be made.

4. *Intermediate-term risk*. Intermediate and long-term residential exposure is not expected for trifluralin and thus no such risk is expected from the use of trifluralin.

5. *Cancer risk*. When using the Q_1* approach to assess a pesticide, the Agency considers all exposure to be additive to aggregate carcinogenic risk, regardless of exposure route or exposure duration (per season). For trifluralin, this means that the chronic exposure from foods (0.000022 mg/kg/day) is added to chronic exposure due to drinking water (0.000008 mg/kg/day) and this in turn is added to exposure estimated for residential use. Based on this assumption, carcinogenic risk estimates are made for those applying trifluralin themselves, each season, throughout adulthood (50 years).

The exposure and carcinogenic risk estimates for residential applicators vary significantly depending on the application method, even if other inputs (rate and area treated) remain the same. Since the carcinogenic risk assessment attempts to reflect long-term exposure, the most appropriate exposure estimate would be based on the most common application method; the push-type spreader (for homeowners).

The risk estimate represents the probability of ''excess'' cancers attributable to trifluralin. In general, the Agency considers carcinogenic risk estimates in the range of 10^{-6}, or less, to be negligible. Applying the Q_1* of 5.8 x 10^{-3} $(mg/kg/day)^{-1}$ to the exposure value, results in a cancer risk estimate of 1.64 x 10^{-7} (DEEM-FCID) and 1.13 x 10^{-7} (Lifeline). Therefore, estimated cancer risk is below the Agency's level of concern.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to trifluralin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (GC method; TFN0291) using an electron capture detector (ECD), Eli Lilly Method AM-AA-CA-R023-AA-755, and GRM 92.11) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of trifluralin in mint oil or in/on spearmint and peppermint tops. Furthermore, no maximum MRLs for trifluralin have been established or proposed by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

C. Conditions

Currently, there are no additional requirements. Also, all existing tolerances are being maintained at current levels and are considered to be reassessed by the Trifluralin Tolerance Reassessment Eligibility Decision signed on August 31, 2004.

V. Conclusion

A tolerance is proposed for residues of trifluralin in mint oil at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This proposed rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any

enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Because this action will not have an adverse impact on small business, I certify, under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that this action will not have a significant economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 16, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 would continue to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.207 would be amended by revising the table in paragraph (a) to read as follows:

§ 180.207 Trifluralin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Alfalfa, hay	0.2
Asparagus	0.05
Barley, hay	0.05
Barley, straw	0.05
Bean, mung, sprouts	2.0
Carrot, roots	1.0
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Cotton, undelinted seed	0.05
Cress, upland	0.05
Flax, seed	0.05
Friut, citrus, group 10	0.05
Fruit, stone, group 12	0.05
Grain, crop, except corn, sweet and rice grain	0.05
Grape	0.05
Hop	0.05
Legume, forage	0.05
Nut, tree, group 14	0.05
Peanut	0.05
Peppermint oil	2.0
Peppermint, tops	0.05
Rapeseed, seed	0.05
Safflower, seed	0.05
Sorghum, forage	0.05
Sorghum, grain, stover	0.05
Spearmint oil	2.0
Spearmint, tops	0.05
Sugarcane, cane	0.05
Sunflower, seed	0.05
Vegetable, cucurbit, group 9	0.05
Vegetable, fruiting, group 8	0.05
Vegetables, leafy	0.05
Vegetables, root (exc. carrots)	0.05
Vegetables, seed and pod	0.05
Wheat, grain	0.05
Wheat, straw	0.05

* * * * *

[FR Doc. 04–25941 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–S

Notices

Federal Register
Vol. 69, No. 226
Wednesday, November 24, 2004

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–085–1]

Monsanto Co. and Forage Genetics International; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Monsanto Company and Forage Genetics International seeking a determination of nonregulated status for alfalfa designated as events J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting public comments on whether this alfalfa presents a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments we receive on or before January 24, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–085–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–085–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–085–1'' on the subject line.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.

Reading Room: You may read the petition, the environmental assessment, and any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Virgil Meier, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–3363. To obtain copies of the petition or the environmental assessment (EA), contact Ms. Terry Hampton at (301) 734–5715; e-mail: *Terry.A.Hampton@aphis.usda.gov*. The petition and the EA are also available on the Internet at *http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf* and *http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_ea.pdf*.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered ''regulated articles.''

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

On April 16, 2004, APHIS received a petition from Monsanto Company of St. Louis, MO, and Forage Genetics International of West Salem, WI (Monsanto/FGI), requesting a determination of nonregulated status under 7 CFR part 340 for alfalfa (*Medicago sativa* L.) designated as events J101 and J163, which have been genetically engineered for tolerance to the herbicide glyphosate. The Monsanto/FGI petition states that the subject alfalfa should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, alfalfa events J101 and J163 have been genetically engineered to express a 5-enolpyruvyshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confers tolerance to the herbicide glyphosate. Expression of the added genes is controlled in part by the 35S promoter derived from the plant pathogen figwort mosaic virus. The *Agrobacterium tumefaciens* transformation method was used to transfer the added genes into the proprietary alfalfa line R2336.

Alfalfa events J101 and J163 have been considered regulated article under the regulations in 7 CFR part 340 because they contain gene sequences from plant pathogens. In the process of reviewing the notifications for field trials of the subject alfalfa, APHIS determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive and physical confinement or isolation, would not present a risk of plant pest introduction or dissemination.

In section 403 of the Plant Protection Act (7 U.S.C. 7701–7772), plant pest is

defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In cases in which genetically modified plants allow for a new use of a pesticide or involve a different use pattern for the pesticide, EPA must approve the new or different use. Accordingly, Monsanto/FGI are seeking registration for the use of glyphosate on glyphosate-tolerant alfalfa from the EPA.

When the use of the pesticide on the genetically modified plant would result in an increase in the residues in a food or feed crop for which the pesticide is currently registered, or in new residues in a crop for which the pesticide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by EPA under the FFDCA. EPA is currently evaluating the residue tolerance for glyphosate-tolerant alfalfa.

FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984–23005). The FDA statement of policy includes a discussion of FDA's authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived from new plant varieties, including those plants developed through the techniques of genetic engineering. Monsanto/FGI has begun consultation with FDA on the subject alfalfa event.

To provide the public with documentation of APHIS' review and analysis of the environmental impacts and plant pest risk associated with a proposed determination of nonregulated status for the Monsanto/FGI events J101 and J163 alfalfa, an environmental assessment (EA) has been prepared. The EA was prepared in accordance with (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested persons on the EA prepared to examine any environmental impacts of the proposed determination for the subject alfalfa event. The petition and the EA and any comments received are available for public review, and copies of the petition and the EA are available as indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. After reviewing and evaluating the comments on the petition and the EA and other data and information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of the Monsanto/FGI glyphosate-tolerant alfalfa events J101 and J163 and the availability of APHIS' written decision.

Authority: 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 18th day of November 2004.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–3315 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–076–2]

Monsanto Co.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Cotton Genetically Engineered for Tolerance to the Herbicide Glyphosate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of the availability of an addendum to a petition from Monsanto Company seeking a determination of nonregulated status for cotton designated as MON 88913, which has been genetically engineered for tolerance to the herbicide glyphosate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting public comments on whether this cotton presents a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status. The content of the addendum does not impact the environmental assessment. However, the information contained within the addendum may add clarity to the review of the petition by the public.

DATES: We will consider all comments we receive on or before December 3, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–076–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–076–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.

Reading Room: You may read the amended petition, the environmental assessment, and any comments that we receive on this docket in our reading

room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Mr. Michael Blanchette, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5141. To obtain copies of the amended petition or the environmental assessment, contact Ms. Terry Hampton at (301) 734–5715; e-mail: *Terry.A.Hampton@aphis.usda.gov.* The amended petition and environmental assessment are also available on the Internet at *http://www.aphis.usda.gov/brs/aphisdocs/04_08601p.pdf* and *http://www.aphis.usda.gov/brs/aphisdocs/04_08601p_ea.pdf.*

SUPPLEMENTARY INFORMATION: On October 4, 2004, we published a notice in the **Federal Register** (69 FR 59181–59182, Docket No. 04–076–1) in which we advised the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from Monsanto Company of St. Louis, MO (Monsanto) seeking a determination of nonregulated status for cotton designated as MON 88913, which has been genetically engineered for tolerance to the herbicide glyphosate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, our notice solicits public comments on whether this cotton presents a plant pest risk. In the notice, we also made available for public comment an environmental assessment (EA) for the proposed determination of nonregulated status. As stated in that notice, we will consider all comments we receive on or before December 3, 2004.

On November 8, 2004, APHIS received a letter from Monsanto amending the petition made available for public comment in our October 4, 2004, notice. The information in the addendum clarifies information in the petition with respect to the molecular genetic characterization of the inserted DNA and corrects portions of that section. APHIS promptly reviewed these changes and determined that they had no impact on the EA we prepared to examine any environmental impacts of the proposed determination for the subject cotton. The addendum has been added to the petition file and is available to facilitate the review of the petition.

We continue to solicit written comments from interested persons on the petition and the EA. In addition to the amended petition, the EA and any comments received are available for public review. Copies of the amended petition and the EA are available as indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. After reviewing and evaluating the comments on the petition and the EA and other data and information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Monsanto's glyphosate-tolerant MON 88913 cotton and the availability of APHIS' written decision.

Authority: 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 18th day of November 2004.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–3316 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–117–1]

General Conference Committee of the National Poultry Improvement Plan; Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: We are giving notice of a meeting of the General Conference Committee of the National Poultry Improvement Plan.

DATES: The meeting will be held on January 26, 2005, from 1:30 to 5 p.m.

ADDRESSES: The meeting will be held at the Georgia World Congress Center, Room C108, 285 Andrew Young International Boulevard NW., Atlanta, GA.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew R. Rhorer, Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, 1498 Klondike Road, Suite 101, Conyers, GA 30094, (770) 922–3496.

SUPPLEMENTARY INFORMATION: The General Conference Committee (the Committee) of the National Poultry Improvement Plan (NPIP), representing cooperating State agencies and poultry industry members, serves an essential function by acting as liaison between the poultry industry and the Department in matters pertaining to poultry health. In addition, the committee assists the Department in planning, organizing, and conducting the NPIP Biennial Conference.

Topics for discussion at the upcoming meeting include:

1. H5/H7 low pathogenic avian influenza program for commercial layers, broilers, and turkeys;
2. Compartmentalization of notifiable avian influenza free zones;
3. National animal identification program for poultry; and
4. Cleaning, disinfection, and bird disposal costs for commercial poultry flocks.

The meeting will be open to the public. However, due to time constraints, the public will not be allowed to participate in the discussions during the meeting. Written statements on meeting topics may be filed with the Committee before or after the meeting by sending them to the person listed under **FOR FURTHER INFORMATION CONTACT**. Written statements may also be filed at the meeting. Please refer to Docket No. 04–117–1 when submitting your statements.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act.

Done in Washington, DC, this 17th day of November 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–3314 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator, Foreign Agricultural Service (FAS), today terminated the certification of a petition for trade adjustment assistance (TAA) that was filed by the Catfish Farmers of America and certified on November 25, 2003. Catfish producers in Alabama, Arkansas, Florida, Georgia, Idaho, Illinois, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nevada, North Carolina, Ohio, Oklahoma, South Carolina, Texas, and Utah will not be eligible for TAA benefits in fiscal year 2005.

SUPPLEMENTARY INFORMATION: Upon investigation, the Administrator determined that domestic producer prices did not decline at least 20 percent during the 2003 marketing year (January–December), when compared to average prices during the 5-year base period ending December 2001. In addition, during the 2003 marketing year, imports did not increase, but declined by 16.2 percent. Both conditions, a decline in prices of at least 20 percent and an increase in imports, are required for re-certifying a petition for TAA.

FOR FURTHER INFORMATION, CONTACT: Jean-Louis Pajot, Coordinator, Trade Adjustment Assistance for Farmers, FAS, USDA, (202) 720–2916, e-mail: *trade.adjustment@fas.usda.gov*.

Dated: November 10, 2004.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 04–26085 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator, Foreign Agricultural Service (FAS), re-certified the trade adjustment assistance (TAA) petition that was filed by the Georgia Shrimp Association on behalf of Georgia shrimpers and initially certified on November 19, 2003. Shrimpers who land their catch in Georgia will be eligible to apply for fiscal year 2005 benefits during a 90-day period beginning on November 29, 2004. The application period closes on February 28, 2005.

SUPPLEMENTARY INFORMATION: Upon investigation, the Administrator determined that continued increases in imports of like or directly competitive products contributed importantly to a decline in the average landed price of shrimp in Georgia by 37.7 percent during the 2003 marketing period (January-December), compared to the 1997–2001 base period. Eligible producers may request technical assistance from the Extension Service at no cost and receive an adjustment assistance payment, if certain program criteria are satisfied. Producers in fiscal year 2005 who did not receive technical assistance under the fiscal year 2004 TAA program must obtain the technical assistance from the Extension Service by May 31, 2005, in order to be eligible for financial payments.

Producers of raw agricultural commodities wishing to learn more about TAA and how they may apply should contact the Department of Agriculture at the addresses provided below for General Information.

Producers Certified as Eligible for TAA, Contact: Farm Service Agency service centers.

For General Information About TAA, Contact: Jean-Louis Pajot, Coordinator, Trade Adjustment Assistance for Farmers, FAS, USDA, (202) 720–2916, e-mail: *trade.adjustment@fas.usda.gov*.

Dated: November 10, 2004.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 04–26086 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Extension of Comment Period; Application for Transportation and Utility Systems and Facilities for the Village at Wolf Creek Draft Environmental Impact Statement

AGENCY: Forest Service, Rio Grande National Forest.

ACTION: Extension of comment period.

SUMMARY: The United States Department of Agriculture (USDA) Forest Service (USFS), Rio Grande National Forest (RGNF) announces the extension of the comment period for the Application for Transportation and Utility Systems and Facilities for the Village at Wolf Creek Draft Environmental Impact Statement (EIS). The comment period ends December 6, 2004.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Robert Dalrymple, Forest Planner, USDA–USFS, Rio Grande National Forest, (719) 852–5941.

Dated: November 16, 2004.

Peter L. Clark,

Forest Supervisor.

[FR Doc. 04–26052 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest, Bearlodge Ranger District, Wyoming, Dean Project Area Proposal and Analysis

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement on a proposal to implement multiple resource management actions within the Dean Area as directed by the Black Hills National Forest Land and Resource Management Plan. The Dean Project Area covers about 12,468 acres of National Forest System land and about 2,256 acres of interspersed private land within the Redwater Creek watershed directly north of Sundance, Wyoming. Proposed actions would modify the structure of forest stands across the planning area to reduce fuel loads, potential for uncharacteristically intense wildfire behavior, and risk of insect outbreaks; provide for diverse wildlife habitat and restore hardwoods; and provide a mix of motorized and non-motorized use opportunities.

DATES: Comments concerning the scope of the analysis must be received by December 22, 2004. The draft environmental impact statement is expected to be available for public review by March 2005 and the final environmental impact statement is expected to be completed by June 2005.

ADDRESSES: Send written comments to Steve Kozel, District Ranger, Black Hills National Forest, Bearlodge Ranger District, 121 S. 21st Street, Sundance, Wyoming 82729. Telephone Number: (307) 283–1361. E-mail: *comments-rocky-mountain-black-hills-bearlodge@fs.fed.us* with ''Dean Project'' as subject.

FOR FURTHER INFORMATION CONTACT: Janis Bouma, Project Coordinator, Black Hills National Forest, Bearlodge Ranger District, at above address, phone (307) 283–1361.

SUPPLEMENTARY INFORMATION: The actions are proposed in direct response to management direction provided by the Black Hills National Forest Land and Resource Management Plan (Forest Plan). The site-specific actions are based on Forest Plan Standards and

Guidelines to promote existing resource conditions in the Dean Project Area toward meeting Forest Plan Goals and Objectives. The project area lies in the Bear Lodge Mountains in the Black Hills National Forest, directly north of Sundance, Wyoming. Anticipated issues include: Fire and fuels hazard in the project area; support and opposition to vegetation treatment such as timber harvest; impacts of vegetation treatment and multiple forest uses on wildlife habitat; motorized and non-motorized recreation; and travel management.

Purpose of and Need for Action

There is a need to reduce the potential for uncharacteristically intense wildlife behavior and insect infestation, provide diverse wildlife habitat, and manage motorized recreation in the Dean Project Area. This project will address Forest Plan Goal 2 (providing for biologically diverse ecosystems) and Goal 3 (providing for sustained commodity uses) consistent with Forest Plan Standards and Guidelines.

Proposed Action

Actions proposed in the Dean Project Area include:

- Modifying stand structure across the planning area to reduce potential for uncharacteristically intense wildfire behavior and benefit wildlife. This action includes thinning the forest, removing conifers from stands of hardwoods such as aspen, bur oak, and birch, and expanding and/or creating meadows.
- Reducing fuel loads by decreasing the volume and arrangement of both existing fuels and those resulting from other vegetation treatment activities. Treatment could include lopping, chipping, crushing, piling and burning, and prescribed burning on up to 3,494 acres.
- Reducing the density of pine stands on up to 5,730 acres to decrease the potential for spreading crown fires, increase tree growth and vigor, and lessen the risk of insect infestation and disease. This may be done by using commercial timber harvest to thin out merchantable trees and using other methods to thin small, unmerchantable trees. These actions would provide wood fiber to local industry and would require construction of up to 10 miles of new specified roads.
- Modifying the Forest Plan through a non-significant Amendment to change Management Area (MA) designation in part of the project area to better reflect actual conditions. The entire project area is currently in MA 5.4 (Big Game Winter Range Emphasis). The lower elevations and south aspects on the east side of the project area currently provide appropriate and important winter range for deer and elk and are utilized as such. However, the remainder of the project area is heavily used by deer and elk only during the spring, summer, and fall, including calving and fawning periods. Therefore, the Forest proposes to change the Management Area designation in a portion of the project area to MA 5.6 (Forest Products, Recreation, and Big Game Emphasis) to reflect the actual utilization and better manage the project area to benefit a variety of wildlife, including big game species, and better reflect existing non-motorized recreation opportunities.
- Providing a mix of motorized and non-motorized opportunities and protecting wildlife in the area by closing the project area to off-road motorized travel and restricting ATV use to designated routes. Main system routes currently open to motorized travel would remain open. Approximately 16.1 miles of roads would also be decommissioned.

Responsible Official

Steve Kozel, District Ranger, Black Hills National Forest, Bearlodge Ranger District, 121 S. 21st Street, Sundance, Wyoming 82729.

Nature of Decision To Be Made

The decision to be made is whether or not to implement the proposed action or alternatives at this time.

Scoping Process

Comments and input regarding the proposal will be requested via direct mailing from the public, other groups and agencies during the 30-day (plus) public comment period in November and December 2004. Also, response to the draft EIS will be sought from the interested public in March 2005.

Comment Requested

This notice of intent initiates the scoping process which guides the development of the environmental impact statement. It is our desire to involve interested parties and especially adjacent landowners in identifying the issues related to proposed activities. Comments will assist the planning team identify key issues and opportunities used to develop project alternatives and mitigation measures.

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A draft environmental impact statement will be prepared for comment. The comment period on the draft environmental impact statement will last 45 days (beginning around March 1, 2005) from the date the Environmental Protection Agency publishes the Notice of Availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21)

Dated: November 17, 2004.

Brad Exton,

Acting Forest Supervisor.

[FR Doc. 04–25972 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Willamette Province Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Willamette Province Advisory Committee (PAC) will meet in Salem, Oregon. The purpose of the meeting is to discuss issues pertinent to the implementation of the Northwest Forest Plan and to provide advice to federal land managers in the Province. The topics to be covered at the meeting include status of BLM Resource Management Plan revisions, update on recent spotted owl studies, selection of projects for Province implementation monitoring, and information sharing.

DATES: The meeting will be held December 9, 2004.

ADDRESSES: The meeting will be held at the Salem District Office of the Bureau of Land Management, 1717 Fabry Road, Salem, Oregon. Send written comments to Neal Forrester, Willamette Province Advisory Committee, c/o Willamette National Forest, P.O. Box 10607, Eugene, Oregon 97440, (541) 225–6436 or electronically to *nforrester@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Neal Forrester, Willamette National Forest, (541) 225–6436.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Committee discussion is limited to PAC members. However, persons who wish to bring matters to the attention of the Committee may file written statements with the PAC staff before or after the meeting. A public forum will be provided and individuals will have the opportunity to address the PAC. Oral comments will be limited to three minutes.

Dated: November 18, 2004.

Y. Robert Iwamoto,

Deputy Forest Supervisor, Willamette National Forest.

[FR Doc. 04–26018 Filed 11–23–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Producing Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration (EDA).

ACTION: To give all interested parties an opportunity to comment.

Petitions have been accepted for filing on the dates indicated from the firms listed below.

LIST OF PETITION ACTION BY TRADE ADJUSTMENT ASSISTANCE FOR PERIOD SEPTEMBER 14, 2004–NOVEMBER 19, 2004

Firm name	Address	Date petition accepted	Product
Hart Associates, Inc	2900 McDonald Avenue Ruston, LA 71270.	14–Sep–04	Brass lamps.
Etron, Inc	1410 Peruville Road, Freeville, NY 14852.	20–Oct–04	Microcomputer programmable controllers used as variable speed vacuum controllers and drives.
Pallet Services, Inc	7422 Wards Road, Lynchburg, VA 24506.	04–Nov–04	Wood pallets and boxes.
Aromaland, Inc	1326 Rufina Circle, Santa Fe, NM 87507.	05–Nov–04	Preparations for use on the hair and skin.
McAllister Tool & Machine, Inc	3410 6th Avenue, Huntsville, AL 35805.	05–Nov–04	Machined parts of aluminum and brass used in relief and check valves.
Ramcel Engineering Company	2926 MacArthur Blvd., Northbrook, IL 60062.	08–Nov–04	Stamped metal components for office machines, automobiles, power tools and tooling for stamping and forming metal.
Gambit Corporation	586 Martin Avenue, Rohnert Park, CA 94928.	09–Nov–04	Custom metal small precision stamping, *i.e.* fourslide parts, wire and strip metal formings, flat springs, clips, contacts, brackets, terminals, pins, probes, dot matrix, print wires.

The petitions were submitted pursuant to section 251 of the Trade Act of 1974 (19 U.S.C. 2341). Consequently, the United States Department of Commerce has initiated separate investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm. Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by Trade Adjustment Assistance, Room 7315, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than the close of business of the tenth calendar day following the publication of this notice. The Catalog of Federal Domestic Assistance official program number and title of the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance.

Dated: November 18, 2004.

Anthony J. Meyer,

Senior Program Analyst, Office of Strategic Initiatives.

[FR Doc. 04–26019 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Action Affecting Export Privileges; Halear, Inc.

In the Matter of: Halear, Inc., 530 North Firestone Lane, Placentia, California 92870; Respondent

The Bureau of Industry and Security, United States Department of Commerce (''BIS'') having notified Halear, Inc., (''Halear'') of its intention to initiate an administrative proceeding against Halear pursuant to section 766.3 of the Export Administration Regulations (currently codified at 15 CFR parts 730–774 (2004)) (''Regulations''),[1] and section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. 2401–2420 (2000)) (''Act''),[2] based on the proposed charging letter issued to Halear that alleged that Halear, during the time period of 1998 to 2001, doing business as Preston Scientific, committed nine violations of the Regulations. Specifically, the charges are:

1. *15 CFR 764.2(a)—Export of an Amplifier to India Without the Required Department of Commerce License:* On or about November 30, 1998, Halear export an amplifier (ECCN 3A992)[3] from the United States to an organization in India on BIS' Entity List[4] without the Department of Commerce license required by section 744.11 of the Regulations.

2. *15 CFR 764.2(e)—Selling and Transferring an Item With Knowledge a Violation of the Regulations Would Occur:* On or about November 30, 1998, Halear sold and transferred the amplifier referenced in Paragraph One above with knowledge that a violation of the Regulations would occur. Specifically, Halear sold and transferred the amplifier to an organization in India on BIS' Entity List when Halear know that the required Department of Commerce license would not be obtained.

3. *15 CFR 764.2(g)—False Statement on a Shipper's Export Declaration Concerning Authority to Export:* On or about December 1, 1998, in connection with the transaction referenced in Paragraph One above, Halear filed or caused to be filed a Shipper's Export Declaration with the U.S. Government for the export of the amplifier to an organization in India on BIS' Entity List that stated the amplifier qualified for export from the United States as NLR (''No License Required''). This statement was false because, as described in Paragraph One above, a Department of Commerce license was required to export the amplifier.

4. *15 CFR 764.2(g)—False Statement to an Office of Export Enforcement Special Agent in the Course of an Investigation:* On or about January 25, 2001, in connection with an ongoing BIS, Office of Export Enforcement (''OEE'') investigation concerning the transaction referenced in Paragraph One above, Halear made a false statement to OEE investigators. Specifically, Halear stated to OEE investigators that the export of the amplifier had been made prior to the imposition of sanctions against India and Pakistan on November 19, 1998, that gave rise to the license requirements in this case. This statement was false because the export was not made until after the imposition of the sanctions.

5. *15 CFR 764.2(a)—Export of a Connector Socket Without the Required Department of Commerce License:* On or about February 26, 1999, Halear exported a connector socket (EAR99)[5] from the United States, through a distributor in India, to an organization in India on BIS' Entity List without the Department of Commerce license required by section 744.11 of the Regulations.

6. *15 CFR 764.2(e)—Selling and Transferring an Item With Knowledge a Violation of the Regulations Would Occur:* On or about February 26, 1999, Halear sold and transferred the connector socket referenced in Paragraph Five above with knowledge that a violation of the Regulations would occur. Specifically, Halear sold and transferred the connector socket to an organization in India on BIS' Entity List when Halear knew that the required Department of Commerce license would not be obtained.

7. *15 CFR 764.2(a)—Export of Spare Parts without the Required Department of Commerce License:* On or about July 29, 1999, Halear exported spare parts (EAR99) from the United States, through a distributor in India, to an organization in India on BIS' Entity List without obtaining a license from the Department of Commerce as required by section 744.11 of the Regulations. In so doing, Halear committed one violation of section 764.2(a) of the Regulations.

8. *15 CFR 764.2(e)—Selling and Transferring Items With Knowledge a Violation of the Regulations Would Occur:* On or about July 29, 1999, Halear sold and transferred the spare parts referenced in Paragraph Seven above with knowledge that a violation of the Regulations would occur. Specifically, halear sold and transferred the spare parts to an organization in India on BIS' Entity List when Halear knew that the required Department of Commerce license would not be obtained.

9. *15 CFR 764.2(g)—False Statement to an Office of Export Enforcement Special Agent in the Course of an Investigation:* On or about January 25, 2001, in connection with an ongoing BIS, OEE investigation concerning the transactions referenced in Paragraphs Five and Seven above, Halear made a false statement to OEE investigators. Specifically, Halear stated to OEE investigators that he had not shipped any items to India since December 1998. This statement was false because Halear had exported items to India after December 1998, as described in Paragraphs Five and Seven above.

BIS and Halear having entered into a Settlement Agreement pursuant to section 766.18(a) of the Regulations whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein, and the terms of the Settlement Agreement having been approved by me;

It is Therefore Ordered:

First, that a civil penalty of $60,000 is assessed against Halear which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of this Order. Payment shall be made in the manner specified in the attached instructions.

Second, that, pursuant to the Debt Collection Act of 1982, as amended (31 U.S.C. 3701–3720E (2000)), the civil penalty owed under this Order accrues interest as more fully described in the attached Notice, and, if payment is not made by the due date specified herein, Halear will be assessed, in addition to the full amount of the civil penalty and

[1] The charged violations occurred from 1998 to 2001. The Regulations governing the violations at issue are found in the 1998 to 2001 versions of the Code of Federal Regulations (15 CFR parts 730–774 (1998–2001)). The 2004 Regulations set forth the procedures that apply to this matter.

[2] From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 CFR, 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706 (2000)) (''IEEPA''). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR 2001 Comp. 783 (2002)), as extended by the Notice of August 6, 2004 (69 FR 48763 (August 10, 2004)), has continued the Regulations in effect under the IEEPA.

[3] The term ''ECCN'' refer to an Export Control Classification Number. *See* Supp. 1 to 15 CFR 774.

[4] *See* Supplement No. 4 to part 744 of the Regulations.

[5] The term ''EAR99'' refers to items subject to the Regulations which are not listed on the Commerce Control List. *See* 15 CFR 734.3(c).

interest, a penalty charge and an administrative charge, as more fully described in the attached Notice.

Third, that the timely payment of the civil penalty set forth above is hereby made a condition to the granting, restoration, or continuing validity of any export license, License Exception, permission, or privilege granted, or to be granted, to Halear. Accordingly, if Halear should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of Halear's export privileges for a period of one year from the date of entry of this Order.

Fourth, that for a period of three years from the date of this Order, Halear, Inc., 530 North Firestone Lane, Placentia, California, 92870 (''Halear''), and when acting for or on behalf of Halear, its representatives, agents, assigns or employees (''denied person'') may not, directly or indirectly, participate in any way in transaction involving any commodity, software, or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Fifth, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the denied person any item subject to the Regulations;

B. Take any action that facilities the acquisition or attempted acquisition by the denied person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the denied person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the denied person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the denied person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the denied person, or service any item, of whatever origin, that is owned, possessed or controlled by the denied person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Sixth, that after notice and opportunity for comment as provided in section 766.23 of the Regulations, any person, firm, corporation, or business organizations related to Halear by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order.

Seventh, that this Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

Eighth, that this Order shall be served on the Denied Person and on BIS, and shall be published in the **Federal Register.**

Ninth, that the proposed charging letter, the Settlement Agreement, and this Order shall be made available to the public.

This order, which constitutes the final agency action in this matter, is effective immediately.

Entered this 18th day of November 2004.

Julie L. Salcido,

Acting Deputy Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 04–25987 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–DT–M

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Action Affecting Export Privileges; Order Relating to Bernard A. Spear

In the Matter of: Bernard A. Spear, 530 North Firestone Lane, Placentia, California 92870, Respondent

The Bureau of Industry and Security, United States Department of Commerce (''BIS'') having notified Bernard A. Spear (''Spear'') of its intention to initiate an administrative proceeding against Spear pursuant to Section 766.3 of the Export Administration Regulations (currently codified at 15 CFR parts 730–774 (2004)) (''Regulations''),[1] and section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. sections 2401–2420 (2000)) (''Act''),[2] based on the proposed charging letter issued to Spear that alleged that, during the time period of 1998 to 2001, Spear, as President of Halear, Inc., doing business as Preston Scientific, in his individual capacity committed nine violations of the Regulations. Specifically, the charges are:

1. 15 CFR 764.2(a)—Export of an Amplifier to India Without the Required Department of Commerce License: On or about November 30, 1998, Spear exported an amplifier (ECCN 3A992)[3] from the United States to an organization in India on BIS' Entity List[4] without the Department of Commerce license required by Section 744.11 of the Regulations.

2. 15 CFR 764.2(e)—Selling and Transferring an Item With Knowledge a Violation of the Regulations Would Occur: On or about November 30, 1998, Spear sold and transferred the amplifier

[1] The charged violations occurred from 1998 to 2001. The Regulations governing the violations at issue are found in the 1998 to 2001 versions of the Code of Federal Regulations (15 CFR parts 730–774 (1998–2001)). The 2004 Regulations set forth the procedures that apply to this matter.

[2] From August 21, 1994 through November 12, 2000, the Act was in lapse During that period, the President, through Executive Order 12924, which had been extended by successive Presidential Notices, the last of which was August 3, 2000 (3 CFR, 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706 (2000)) (''IEEPA''). On November 13, 2000, the Act was reauthorized and it remained in effect through August 20, 2001. Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), as extended by the Notice of August 6, 2004 (69 FR 48763 (August 10, 2004)), has continued the Regulations in effect under the IEEPA.

[3] The term ''ECCN'' refers to an Export Control Classification Number. *See* Supp. 1 to 15 CFR 774.

[4] *See* Supplement No. 4 to Part 744 of the Regulations.

referenced in Paragraph One above with knowledge that a violation of the regulations would occur. Specifically, Spear sold and transferred the amplifier to an organization in India on BIS' Entity List when Spear know that the required Department of Commerce license would not be obtained.

3. 15 CFR 764.2(g)—False Statements on a Shipper's Export Declaration Concerning Authority to Export: On or about December 1, 1998, in connection with the export referenced in Paragraph One above, Spear filed or caused to be filed a Shipper's Export Declaration with the U.S. government for the export of the amplifier to an organization in India on BIS' Entity List that stated it qualified for export from the United States as NLR (''No License Required''). This statement was false because, as described in Paragraph One above, a Department of Commerce license was required to export the amplifier.

4. 15 CFR 764.2(g)—False Statement to an Office of Export Enforcement Special Agent in the Course of an Investigation: On or about January 25, 2001, in connection with an ongoing BIS, Office of Export Enforcement (''OEE'') investigation concerning the transactions referenced in Paragraph One above, Spear made a false statement to OEE investigators. Specifically, Spear stated to OEE investigators that the export of the amplifier had been made prior to the imposition of sanctions against India and Pakistan on November 19, 1998, that gave rise to the license requirements in this case. This statement was false because the export was not made until after the imposition of the sanctions.

5. 15 CFR 764.29a)—Export of a Connector Socket Without the Required Department of Commerce License: On or about February 26, 1999, Spear exported a connector socket (EAR99)[5] from the United States, through a distributor in India, to an organization in India on BIS' Entity List without the Department of Commerce license required by Section 744.11 of the Regulations.

6. 15 CFR 764.2(e)—Selling and Transferring an Item With Knowledge a Violation of the Regulations Would Occur: On or about February 26, 1999, Spear sold and transferred the connector socket referenced in Paragraph Five above with knowledge that a violation of the Regulations would occur. Specifically, Spear sold and transferred the connector socket to an organization in India on BIS' Entity List when Speak knew that the required Department of Commerce license would not be obtained.

7. 15 CFR 764.2(a)—Export of Spare Part Without the Required Department of Commerce License: On or about July 29, 1999, Spear exported spare parts (EAR99) from the United States, through a distributor in India, to an organization in India on BIS' Entity List without obtaining a license from the Department of the Commerce as required by Section 744.11 of the Regulations.

8. 15 CFR 764.2(e)—Selling and Transferring Items With Knowledge a Violation of the Regulations Would Occur: On or about July 29, 1999, Spear sold and transferred the spare parts referenced in Paragraph Seven above with knowledge that a violation of the Regulations would occur. Specifically, Spear sold and transferred the spare parts to an organization in India on BIS' Entity List when Speak knew that the required Department of Commerce license would not be obtained.

9. 15 CFR 764.2(g)—False Statement to an Office of Export Enforcement Special Agent in the Course of an Investigation: On or about January 25, 2001, in connection with an ongoing BIS, OEE investigation concerning the transactions referenced in Paragraphs Five and Seven above, Spear made a false statement to OEE investigators. Specifically, Spear stated to OEE investigators that he had not shipped any items to India since December 1998. This statement was false because Spear had exported items to India after December 1998, as described in Paragraphs Five and Seven above.

BIS and Spear having entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein, and the terms of the Settlement Agreement having been approved by me;

It is therefore ordered:

First, that for a period of three years from the date of this Order, Bernard A. Spear, 530 North Firestone Lane, Placentia, California, 92870 (''Spear''), and when acting for or on behalf of Spear, his representatives, agents, assigns or employees (''denied person'') may not, directly or indirectly, participate in any way in any transaction involving any commodity, software, or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the denied person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the denied person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the denied person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the denied person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the denied person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the denied person, or service any item, of whatever origin that is owned, possessed or controlled by the denied person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, that after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or businesses organization related to Spear by affiliation, ownership, control, or

[5] The term ''EAR99'' refers to items subject to the Regulations which are not listed on the Commerce Control List. See 15 CFR 734.3(c).

position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order.

Fourth, that this Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

Fifth, that the proposed charging letter, the Settlement Agreement, and this Order shall be made available to the public.

Sixth, that this Order shall be served on the Denied Person and on BIS, and shall be published in the **Federal Register**.

This Order, which constitutes the final agency action in this matter, is effective immediately.

Entered this 18th day of November 2004.

Julie L. Salcido,

Acting Deputy Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 04–25988 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–DT–M

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Processing Equipment Technical Advisory Committee; Notice of Open Meeting

The materials Processing Equipment Technical Advisory Committee (MPETAC) will meet on December 16, 2004 at 9 a.m. in Room 6087B of the Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials processing equipment and related technology.

Agenda

1. Opening remarks and introductions.
2. Presentation of papers and comments by the public.
3. Discussion on proposals for 2005 regarding 5-axis machine tools, coordinate measuring machines, optical finishing machines, and contact lens machines.
4. Comments on machine tool licensing. The meeting will be open to the public and a limited number of seats will be available. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to Lee Ann Carpenter at *Lcarpent@bis.doc.gov* For more information, please contact Ms. Carpenter at 202–482–2583.

Dated: November 19, 2004.

Lee Ann Carpenter,

Committee Liaison Officer.

[FR Doc. 04–26043 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–JT–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–802]

Agreement Suspending the Antidumping Investigation on Uranium From the Russian Federation; Correction to the Notice of Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Correction to notice of initiation of antidumping and countervailing duty administrative reviews.

EFFECTIVE DATE: November 24, 2004.

FOR FURTHER INFORMATION CONTACT: Sally Gannon or Jonathan Herzog, Office of Policy and Negotiations, Bilateral Agreements Unit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC 20230; telephone (202) 482–0162 or (202) 482–4271, respectively.

Background

On November 19, 2004, the Department of Commerce (''the Department'') published in the **Federal Register** a notice of the initiation of antidumping and countervailing duty administrative reviews. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 69 FR 67701 (November 19, 2004) (''*Initiation Notice*''). In the *Initiation Notice,* the Department inadvertently listed the initiation of an administrative review of the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation (''Russian uranium suspension agreement''). *See Initiation Notice,* 69 FR at 67701. The Department has not initiated an administrative review of the Russian uranium suspension agreement. Therefore, the *Initiation Notice* is hereby corrected to reflect that the administrative review of the Russian uranium suspension agreement has not been initiated.

This notice is published in accordance with sections 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)), and 19 CFR 351.221(c)(1)(I).

Dated: November 22, 2004.

Holly A. Kuga,

Senior Office Director, Office 4 for Import Administration.

[FR Doc. 04–26176 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–840]

Notice of Final Results of Antidumping Duty Administrative Review: Carbon and Certain Alloy Steel Wire Rod from Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 20, 2004, the Department of Commerce (the Department) published the preliminary results of its first administrative review of the antidumping duty order on carbon and certain alloy steel wire rod from Canada. The review covers one producer of the subject merchandise. The period of review (POR) is April 10, 2002, through September 30, 2003. Based on our analysis of comments received, these final results differ from the preliminary results. The final results are listed below in the Final Results of Review section.

EFFECTIVE DATE: November 24, 2004.

FOR FURTHER INFORMATION CONTACT: Daniel O'Brien or David Neubacher, at (202) 482–1376 or (202) 482–5823, respectively; AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce,14th Street & Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On July 20, 2004, the Department published in the **Federal Register** the preliminary results of the first administrative review of the antidumping duty order on carbon and certain alloy steel wire rod from Canada. *See Notice of Preliminary Results of*

Antidumping Duty Administrative Review: Carbon and Certain Steel Alloy Steel Wire from Canada, 69 FR 43389 (July 20, 2004) (*Preliminary Results*)

We invited parties to comment on the *Preliminary Results*. On September 2, 2004, we received case briefs from the sole respondent, Ivaco, and the petitioners, Gerdau Ameristeel US Inc., Georgetown Steel Company, Keystone Consolidated Industries, Inc., and North Star Steel Texas, Inc. Both parties submitted rebuttal briefs on September 2, 2004. No public hearing was requested.

Scope of the Order

Effective July 24, 2003, in accordance with the Department's *Notice of Final Result of Changed Circumstances Review of the Antidumping Duty and Countervailing Duty Orders, and Intent to Revoke Orders in Part*, 68 FR 64079 (November 12, 2003), the scope of this order was amended. Therefore, for purposes of this review, there were separate scopes in effect. These scopes are set forth below.

Scope of Order from October 29, 2002, through July 23, 2003

The merchandise subject to this order is certain hot–rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter.

Specifically excluded are steel products possessing the above–noted physical characteristics and meeting the *Harmonized Tariff Schedule of the United States* (HTSUS) definitions for (a) stainless steel; (b) tool steel; (c) high nickel steel; (d) ball bearing steel; and (e) concrete reinforcing bars and rods. Also excluded are (f) free machining steel products (i.e., products that contain by weight one or more of the following elements: 0.03 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorus, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium).

Also excluded from the scope are 1080 grade tire cord quality wire rod and 1080 grade tire bead quality wire rod. This grade 1080 tire cord quality rod is defined as: (i) grade 1080 tire cord quality wire rod measuring 5.0 mm or more but not more than 6.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no inclusions greater than 20 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.15 mm; (vi) capable of being drawn to a diameter of 0.30 mm or less with 3 or fewer breaks per ton, and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.006 percent or less of nitrogen, and (5) not more than 0.15 percent, in the aggregate, of copper, nickel and chromium.

This grade 1080 tire bead quality rod is defined as: (i) grade 1080 tire bead quality wire rod measuring 5.5 mm or more but not more than 7.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no inclusions greater than 20 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.2 mm; (vi) capable of being drawn to a diameter of 0.78 mm or larger with 0.5 or fewer breaks per ton; and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of soluble aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.008 percent or less of nitrogen, and (5) either not more than 0.15 percent, in the aggregate, of copper, nickel and chromium (if chromium is not specified), or not more than 0.10 percent in the aggregate of copper and nickel and a chromium content of 0.24 to 0.30 percent (if chromium is specified).

The designation of the products as ''tire cord quality'' or ''tire bead quality'' indicates the acceptability of the product for use in the production of tire cord, tire bead, or wire for use in other rubber reinforcement applications such as hose wire. These quality designations are presumed to indicate that these products are being used in tire cord, tire bead, and other rubber reinforcement applications, and such merchandise intended for the tire cord, tire bead, or other rubber reinforcement applications is not included in the scope. However, should petitioners or other interested parties provide a reasonable basis to believe or suspect that there exists a pattern of importation of such products for other than those applications, end–use certification for the importation of such products may be required. Under such circumstances, only the importers of record would normally be required to certify the end use of the imported merchandise.

All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products under review are currently classifiable under subheadings 7213.91.3010, 7213.91.3090, 7213.91.4510, 7213.91.4590, 7213.91.6010, 7213.91.6090, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0010, 7227.20.0020, 7227.20.0090, 7227.20.0095, 7227.90.6051, 7227.90.6053, 7227.90.6058, and 7227.90.6059 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

Scope of Order from July 24, 2003, through the POR

The merchandise subject to this order is certain hot–rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter.

Specifically excluded are steel products possessing the above–noted physical characteristics and meeting the HTSUS definitions for (a) stainless steel; (b) tool steel; c) high nickel steel; (d) ball bearing steel; and (e) concrete reinforcing bars and rods. Also excluded are (f) free machining steel products (*i.e.*, products that contain by weight one or more of the following elements: 0.03 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorus, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium).

Also excluded from the scope are 1080 grade tire cord quality wire rod and 1080 grade tire bead quality wire rod. This grade 1080 tire cord quality rod is defined as: (i) Grade 1080 tire cord quality wire rod measuring 5.0 mm or more but not more than 6.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non–deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.15 mm; (vi) capable of being drawn to a diameter of 0.30 mm or less with 3 or fewer breaks per ton, and (vii) containing by weight the following

elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.006 percent or less of nitrogen, and (5) not more than 0.15 percent, in the aggregate, of copper, nickel and chromium.

This grade 1080 tire bead quality rod is defined as: (i) grade 1080 tire bead quality wire rod measuring 5.5 mm or more but not more than 7.0 mm in cross-sectional diameter; (ii) with an average partial decarburization of no more than 70 microns in depth (maximum individual 200 microns); (iii) having no non–deformable inclusions greater than 20 microns and no deformable inclusions greater than 35 microns; (iv) having a carbon segregation per heat average of 3.0 or better using European Method NFA 04–114; (v) having a surface quality with no surface defects of a length greater than 0.2 mm; (vi) capable of being drawn to a diameter of 0.78 mm or larger with 0.5 or fewer breaks per ton; and (vii) containing by weight the following elements in the proportions shown: (1) 0.78 percent or more of carbon, (2) less than 0.01 percent of soluble aluminum, (3) 0.040 percent or less, in the aggregate, of phosphorus and sulfur, (4) 0.008 percent or less of nitrogen, and (5) either not more than 0.15 percent, in the aggregate, of copper, nickel and chromium (if chromium is not specified), or not more than 0.10 percent in the aggregate of copper and nickel and a chromium content of 0.24 to 0.30 percent (if chromium is specified).

For purposes of the grade 1080 tire cord quality wire rod and the grade 1080 tire bead quality wire rod, an inclusion will be considered to be deformable if its ratio of length (measured along the axis - that is, the direction of rolling - of the rod) over thickness (measured on the same inclusion in a direction perpendicular to the axis of the rod) is equal to or greater than three. The size of an inclusion for purposes of the 20 microns and 35 microns limitations is the measurement of the largest dimension observed on a longitudinal section measured in a direction perpendicular to the axis of the rod. This measurement methodology applies only to inclusions on certain grade 1080 tire cord quality wire rod and certain grade 1080 tire bead quality wire rod that are entered, or withdrawn from warehouse, for consumption on or after July 24, 2003.

The designation of the products as ''tire cord quality'' or ''tire bead quality'' indicates the acceptability of the product for use in the production of tire cord, tire bead, or wire for use in other rubber reinforcement applications such as hose wire. These quality designations are presumed to indicate that these products are being used in tire cord, tire bead, and other rubber reinforcement applications, and such merchandise intended for the tire cord, tire bead, or other rubber reinforcement applications is not included in the scope. However, should petitioners or other interested parties provide a reasonable basis to believe or suspect that there exists a pattern of importation of such products for other than those applications, end–use certification for the importation of such products may be required. Under such circumstances, only the importers of record would normally be required to certify the end use of the imported merchandise.

All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products under review are currently classifiable under subheadings 7213.91.3010, 7213.91.3090, 7213.91.4510, 7213.91.4590, 7213.91.6010, 7213.91.6090, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0010, 7227.20.0020, 7227.20.0090, 7227.20.0095, 7227.90.6051, 7227.90.6053, 7227.90.6058, and 7227.90.6059 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.[1]

Analysis of Comments Received

The issues raised in the case briefs by parties to this administrative review are addressed in the *Issues and Decision Memorandum* to James J. Jochum, Assistant Secretary for Import Administration, from Jeffrey May, Deputy Assistant Secretary (*Decision Memorandum*), which is hereby adopted by this notice. A list of the issues addressed in the *Decision Memorandum* is appended to this notice. The *Decision Memorandum* is on file in the Central Records Unit in Room B–099 of the main Commerce building, and can also be accessed directly on the Web at www.ia.ita.doc.gov/frn. The paper copy and electronic version of the Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made adjustments to the indirect selling, warehousing and head office expenses used in calculating the final dumping margin in this proceeding. The adjustments are discussed in detail in the *Decision Memorandum*.

Final Results of Review

As a result of our review, we determine that the following weighted–average margin exists for the period of April 10, 2002, through September 30, 2003:

Producer	Weighted–Average Margin (Percentage)
Ivaco	4.16

Assessment

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries, pursuant to 19 CFR 351.212(b). The Department calculated importer–specific duty assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales for that importer. Where the assessment rate is above *de minimis*, we will instruct CBP to assess duties on all entries of subject merchandise by that importer. The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of these final results of review.

Cash Deposits

Furthermore, the following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of carbon and certain alloy steel wire rod from Canada entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751(a) of the Tariff Act of 1930, as amended (the Act): (1) for companies covered by this review, the cash deposit rate will be the rate listed above; (2) for merchandise exported by producers or exporters not covered in this review but covered in the investigation, the cash deposit rate will continue to be the company–specific rate from the final determination; (3) if the exporter is not a firm covered in this review or the investigation, but the producer is, the cash deposit rate will be that established for the producer of the merchandise in these final results of review or in the final determination; and (4) if neither the exporter nor the producer is a firm covered in this review or the investigation, the cash deposit rate will be 8.11 percent, the ''All Others'' rate

[1] Effective January 1, 2004, U.S. Customs and Border Protection (CBP) reclassified certain HTSUS numbers related to the subject merchandise. *See* http://hotdocs.usitc.gov/tariff__chapters__current/toc.html.

established in the less–than-fair–value investigation. These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402 (f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred, and in the subsequent assessment of double antidumping duties.

This notice also is the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 17, 2004.

James J. Jochum,

Assistant Secretary for Import Administration.

APPENDIX

Comment 1: Indirect Selling Expense Ratio

Comment 2: Warehousing Expenses

Comment 3: Purchases from Affiliate

Comment 4: Indirect Selling Expenses Incurred in Canada

Comment 5: Cash Deposit Instructions

Comment 6: Allocation of Head Office Expenses to U.S. Further Manufacturing Expenses

Comment 7: Surrogate Payment Date Applied to Unpaid Sales

Comment 8: Treatment of Negative Margins

Comment 9: Ministerial Error Allegations

[FR Doc. 04–26060 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 111904A]

Proposed Information Collection; Comment Request; National Marine Sanctuary Permits

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before January 24, 2005.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to John Armor, National Marine Sanctuary Program, NOAA, 1305 East-West Highway (N/ORM6), Silver Spring, MD 20910 (or via the Internet at *John.Armor@noaa.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

Persons wishing to conduct otherwise prohibited activities in a National Marine Sanctuary must apply for and receive a permit. Anyone issued permits must file reports on the activity conducted. This information is required to ensure that the proposed activity is consistent with the objectives of the sanctuary, and the reports are needed to ensure compliance with permit conditions and to increase knowledge regarding the sanctuary's resources.

II. Method of Collection

Specific requirements are detailed in various subparts of 15 CFR 922. Persons requesting a permit are sent guidelines for the application process or an application form.

III. Data

OMB Number: 0648–0141.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Not-for-profit institutions; individuals or households; business or other for-profit organizations; and state, local, or tribal government.

Estimated Number of Respondents: 336.

Estimated Time Per Response: 1 hour each for a general permit application, cruise or flight log, and report; 2 hours each for a historical resource permit application, cruise log, and report; 24 hours each for a special use permit application, final report, and financial report; 15 minutes for a permit amendment; 15 minutes each for a baitfish permit application and a logbook; 15 minutes for researcher entries to a research registry; 30 minutes to request certification of a pre-existing lease, license, or permit; 1 hour each for a notification of a request for a permit from another agency, cruise or flight log, and report; and 1.5 hours for a permit appeal.

Estimated Total Annual Burden Hours: 886.

Estimated Total Annual Cost to Public: $800.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 17, 2004.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 04–26058 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–NK–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 041116319–4319–01; I.D. 110504D]

Magnuson-Stevens Act Provisions; Fishing Capacity Reduction Program for the Crab Species Covered by the Fishery Management Plan for the Bering Sea/Aleutian Islands King and Tanner Crabs

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of fishing capacity reduction program payment tender.

SUMMARY: NMFS issues this notice to inform the public about tendering reduction payments to accepted bidders under the Bering Sea/Aleutian Islands King and Tanner Crab fishing capacity reduction program. NMFS has accepted reduction bids, and a successful referendum has approved an industry fee system for repaying the $97.4 million reduction loan financing 100 percent of the program's cost. Accordingly, NMFS is preparing to tender reduction payments to accepted bidders.

ADDRESSES: Send questions about this notice to Michael L. Grable, Chief, Financial Services Division, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3282.

FOR FURTHER INFORMATION CONTACT: Michael L. Grable, (301) 713–2390.

SUPPLEMENTARY INFORMATION:

I. Background

Section 144 of Public Law 106–554 (as amended by section 2201 of Pub. L. 107–20 and section 205 of Public Law 107–117) directed the Secretary of Commerce to establish a $100 million fishing capacity reduction program (program) in the Bering Sea/Aleutian Islands king and Tanner crab fishery (crab fishery). The program's objective is reducing the crab fishery's harvesting capacity. This will help financially stabilize this limited-entry fishery and fosters its future management.

NMFS implemented the program by publishing a proposed rule on December 12, 2002 (67 FR 76329) and a final rule on December 12, 2003 (68 FR 69331). Persons wanting further program details should refer to these rules.

This is a voluntary program in which, in return for reduction payments, bidders whose bids NMFS accepts permanently relinquish their fishing licenses, the fishing histories upon which those licenses' issuance was based, and their vessels' worldwide fishing privileges. Their vessels may never fish again and may never be transferred out of U.S. registry.

The total cost of reduction payments to all accepted bidders (and, thus, the program's total cost) cannot exceed $100 million. This cost is 100 percent financed by a fishing capacity reduction loan from NMFS' Fisheries Finance Program. Future crab landing fees will repay the reduction loan over the next 30 years. Each of six area/species endorsement crab fisheries has a different reduction loan subamount to repay and does so at a fee rate appropriate for each subamount.

Under the program, the holders of non-interim crab fishery licenses make bid offers to NMFS for reduction payments. NMFS scores each bid's reduction payment amount against the amount of the bidder's past ex-vessel crab revenues and, in a reverse auction, accepts those bids whose reduction payments are the lowest percentages of the bidders' revenues during a certain period. NMFS quits accepting bids before acceptance of the bid with the next lowest bid score causes reduction payments to exceed the maximum $100 million program cost. Bid acceptances create reduction contracts whose performance are subject only to a successful referendum about the industry fee system necessary to repay the reduction loan.

The referendum follows the bidding process. Approval of the industry fee system requires at least two-thirds of the qualified voters casting ballots to vote in favor of the industry fee system. Qualified voters are all interim and non-interim holders of crab licenses, except those endorsed only for the Norton Sound area/species crab fishery.

II. Present Status

NMFS has twice invited program bids and administered separate referendums on each of the two accepted bidder results.

NMFS administered and, because of a mistake which overstated the bidding results, readministered a referendum about bids accepted under the first invitation to bid. The readministered referendum was unsuccessful. Because of the circumstances involved, however, NMFS issued a second invitation to bid for which the referendum was successful. This notice involves the program's second invitation to bid and the accepted bids, referendum, and reduction contracts consequent to such second invitation to bid.

NMFS issued the second invitation to bid, and the bidding period opened, on August 6, 2004. This bidding period closed on September 24, 2004. Fifty five, non-interim, crab license holders submitted bids totaling $225,954,284. NMFS accepted 25 bids. These totaled $97,399,357. The next lowest scoring bid would have exceeded the program's $100 million maximum cost. The accepted bids involved 25 fishing vessels and 62 fishing licenses or permits. Twenty five of the permits were non-interim crab fishery licenses. The remaining included 15 groundfish fishing licenses, 20 Federal fishery vessel permits, 1 high seas permit, and 1 halibut individual fishing quota allocation.

On October 1, 2004, NMFS mailed referendum ballots to 313 qualified referendum voters. This referendum involved the fees necessary to repay the $97,399,357 reduction loan resulting from the 25 bids NMFS accepted under the program's second invitation to bid. The second referendum voting period opened on October 1, 2004, and closed on November 15, 2004. Two hundred seventy three (or 87.22 percent) of the referendum's qualified voters cast timely ballots. Two hundred seventeen (or 79.49 percent) of the those ballots approved the fees. This exceeded the two-thirds minimum required for industry fee system approval. This referendum was, consequently, successful and approved the industry fee system. Accordingly, the reduction contracts are now in full force and effect and NMFS is now preparing to tender and disburse reduction payments to accepted bidders.

III. Purpose

NMFS publishes this notification to inform the public before tendering reduction payments to the 25 accepted bidders. NMFS will tender reduction payments on December 27, 2004. When NMFS tenders a reduction payment to an accepted bidder, the bidder must then permanently stop all further fishing with each reduction permit the bidder has relinquished and with the reduction vessel whose worldwide fishing privileges the bidder has relinquished. NMFS will then:

(a) Revoke each reduction permit each accepted bidder relinquished,

(b) Revoke each reduction vessel's fishing history,

(c) Notify the National Vessel Documentation Center to revoke the fishery trade endorsement of each accepted bidder's reduction vessel and otherwise appropriately annotate the reduction vessel's document, and

(d) Notify the U.S. Maritime Administration to prohibit the reduction vessel's transfer to foreign ownership or registry.

Among other things, the reduction contract with each accepted bidder requires the bidder to notify each creditor or other party with an interest in the bidder's reduction vessel or reduction permit that the bidder has entered into a reduction contract which relinquishes the reduction permit and the reduction vessel's fishing privileges in return for NMFS payment to the bidder of a reduction payment. Upon NMFS reduction payment tender, each accepted bidder must, among other things and as a condition of NMFS disbursing the bidder's reduction payment in accordance with the bidder's written payment instruction, also certify to NMFS that the bidder has given such notice to each such creditor or other party.

This notification begins the 30–day period and puts the public (including creditors or other parties) on notice. Section IV of this notification identifies the accepted bidders and the reduction vessels and reduction permits involved in their bids.

IV. Accepted Bidders, Reduction Vessels, and Reduction Permits.

The table below establishes:

(a) The names of the accepted bidders,

(b) The names and official numbers of the reduction vessels whose worldwide fishing privileges the accepted bidders relinquished, and

(c) The license numbers and natures of the reduction permits the accepted bidders relinquished.

BILLING CODE 3510–22–S

ACCEPTED BIDDER	VESSEL NAME	VESSEL OFFICIAL NUMBER	PERMIT FISHERY	PERMIT NUMBER
Aleutian Rover, LLC	Aleutian Rover	517272	Red King Crab, Bristol Bay	LLC3319
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3319
			Blue King Crab, St. Matthew	LLC3319
			Federal Fishery Vessel Permit	5282
American Way Fisheries, Inc.	American Way	662562	Red King Crab, Bristol Bay	LLC1658
			C.Opilio and C. Bairdi Crab, BS/AI	LLC1658
			Blue King Crab, St. Matthew	LLC1658
			Red or Blue King Crab, Pribilof	LLC1658

			Bering Sea Groundfish	LLG1657
			Federal Fishery Vessel Permit	2099
			Halibut Individual Fishing Quota	2458
Arctic Eagle, LLC	Arctic Eagle	967106	Red King Crab, Bristol Bay	LLC3891
			Blue King, St. Matthew	LLC3891
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3891
			Bering Sea Groundfish	LLG3890
			Federal Fishery Vessel Permit	4555
Bering Star, LLC	Morzhovoi	523428	Red King Crab, Bristol Bay	LLC3965
			Blue King Crab, St. Matthew	LLC3965
			Red or Blue King Crab, Pribilof	LLC3965

			C.Opilio and C. Bairdi Crab, BS/AI	LLC3965
Diamond Head, Inc.	Diamond Head	289678	Blue King Crab, St. Matthew	LLC1947
			Red King Crab, Bristol Bay	LLC1947
			C.Opilio and C. Bairdi Crab, BS/AI	LLC1947
			Federal Fishery Vessel Permit	5548
Gene E Watson	Norseman	553713	Red King Crab, Bristol Bay	LLC3297
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3297
			Blue King Crab, St. Matthew	LLC3297
Harlan Dean Jr	Westling	633577	Red King Crab, Bristol Bay	LLC2808
			C.Opilio and C. Bairdi Crab, BS/AI	LLC2808

			Blue King Crab, St. Matthew	LLC2808
			Bering Sea Groundfish	LLG2807
K H Colburn, Inc.	Sirene	615699	C.Opilio and C. Bairdi Crab, BS/AI	LLG3657
			Red King Crab, Bristol Bay	LLC3657
			Blue King Crab, St. Matthew	LLC3657
			Bering Sea Groundfish	LLC3656
			Federal Fishery Vessel Permit	7113
Kodiak Queen, Inc.	Kodiak Queen	507891	Red King Crab, Bristol Bay	LLC3879
			Blue King Crab, St. Matthew	LLC3879
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3879
			Federal Fishery Vessel Permit	603

Labrador Group	Labrador	284504	Red King Crab, Bristol Bay	LLC2037
			C.Opilio and C. Bairdi Crab, BS/AI	LLC2037
			Red or Blue King Crab, Pribilof	LLC2037
			Blue King Crab, St. Matthew	LLC2037
			Bering Sea Groundfish	LLG2036
			Federal Fishery Vessel Permit	4589
Mattsen Fisheries, Inc.	Shaman	558637	Blue King Crab, St. Matthew	LLG2577
			Red King Crab, Bristol Bay	LLC2577
			C.Opilio and C. Bairdi Crab, BS/AI	LLC2577
			Bering Sea Groundfish	LLC2576
			Federal Fishery Vessel Permit	602

Micheal K King	Rebel	596135	Red King Crab, Bristol Bay	LLC3020
			Blue King Crab, St. Matthew	LLC3020
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3020
			Bering Sea Groundfish	LLG4478
			High Seas	596135
			Federal Fishery Vessel Permit	3689
Norseman Fisheries, Inc.	Norseman II	601068	C.Opilio and C. Bairdi Crab, BS/AI	LLC1243
			Red King Crab, Bristol Bay	LLC1243
			Red or Blue King Crab, Pribilof	LLC1243
			Western Gulf Groundfish	LLG1242
			Federal Fishery Vessel Permit	5451

North Pacific, LLC	North Pacific	511698	Brown King Crab, Aleutian Islands	LLC3256
			Red King Crab, Bristol Bay	LLC3256
			Blue King Crab, St. Matthew	LLC3256
			Red or Blue King Crab, Pribilof	LLC3256
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3256
			Bering Sea Groundfish	LLG3255
			Federal Fishery Vessel Permit	4851
Northern Orion, Inc.	Northern Orion	589854	Red King Crab, Bristol Bay	LLC3035
			Blue King Crab, St. Matthew	LLC3035
			Red or Blue King Crab, Pribilof	LLC3035
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3035

			Federal Fishery Vessel Permit	3747
Ocean Viking LLC	Western Viking	507161	Brown King Crab, Aleutian Islands	LLC1229
			Blue King Crab, St. Matthew	LLC1229
			Red or Blue King Crab, Pribilof	LLC1229
			Red King Crab, Bristol Bay	LLC1229
			C.Opilio and C. Bairdi Crab, BS/AI	LLC1229
			Bering Sea Groundfish	LLG1228
			Western Gulf Groundfish	LLG1228
			Federal Fishery Vessel Permit	5131
Profs. Fishermen'S Assoc., Inc.	Stormy Sea	586415	Red King Crab, Aleutian Islands	LLC3106
			Blue King Crab, St. Matthew	LLC3106

			Brown King Crab, Aleutian Islands	LLC3106
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3106
			Red or Blue King Crab, Pribilof	LLC3106
			Red King Crab, Bristol Bay	LLC3106
			Bering Sea Groundfish	LLG3105
			Federal Fishery Vessel Permit	4136
Q & S Enterprises, Inc.	Exito	273458	Red King Crab, Bristol Bay	LLC1817
			Red or Blue King Crab, Pribilof	LLC1817
			Blue King Crab, St. Matthew	LLC1817
			C.Opilio and C. Bairdi Crab, BS/AI	LLC1817
			Bering Sea Groundfish	LLG1816

			Federal Fishery Vessel Permit	5091
Sea Spray, LLC	Sea Spray	522411	Red King Crab, Bristol Bay	LLC2289
			C.Opilio and C. Bairdi Crab, BS/AI	LLC2289
			Blue King Crab, St. Matthew	LLC2289
Seventh Son, Inc.	Lady Jessie	643789	Red King Crab, Bristol Bay	LLC3930
			Blue King Crab, St. Matthew	LLC3930
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3930
			Federal Fishery Vessel Permit	5262
Silent Lady, Inc.	Silent Lady	529872	Red King Crab, Bristol Bay	LLC3326
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3326

			Red or Blue King Crab, Pribilof	LLC3326
			Bering Sea Groundfish	LLG3325
			Federal Fishery Vessel Permit	5328
Sitkin Island, Inc.	Sitkin Island	289317	Red King Crab, Bristol Bay	LLC3033
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3033
			Blue King Crab, St. Matthew	LLC3033
			Federal Fishery Vessel Permit	3743
Susitna Maritime, Inc.	Susitna	603312	C.Opilio and C. Bairdi Crab, BS/AI	LLC3457
			Red or Blue King Crab, Pribilof	LLC3457
			Red King Crab, Bristol Bay	LLC3457
			Blue King Crab, St. Matthew	LLC3457

			Central Gulf Groundfish	LLG3456
			Federal Fishery Vessel Permit	1901
Timothy J Kennedy	Secret Island	969494	Red King Crab, Bristol Bay	LLC3330
			Blue King Crab, St. Matthew	LLC3330
			C.Opilio and C. Bairdi Crab, BS/AI	LLC3330
			Red or Blue King Crab, Pribilof	LLC3330
Zolotoi Partnership	Zolotoi	625095	C.Opilio and C. Bairdi Crab, BS/AI	LLC2920
			Red or Blue King Crab, Pribilof	LLC2920
			Federal Fishery Vessel Permit	3016

Authority: Pub. L. 107–206, Pub. L. 108–7, 16 U.S.C. 1861a (b–e), and 50 CFR 600.1000 *et seq.*

Dated: November 18, 2004.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 04–26059 Filed 11–23–04; 8:45 am]

BILLING CODE 3510–22–C

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textiles and Textile Products Produced or Manufactured in Taiwan; Correction

November 18, 2004.

In the letter to the Commissioner, Bureau of Customs and Border Protection published in the **Federal Register** on November 12, 2004 (69 FR 65414), on page 65415, 2nd column, in the table listing import restraint limits, please insert Categories 338/339 with the limit of 1,054,585 dozen under ''Sublevels in Group II'', as it was inadvertently left out.

James C. Leonard III,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. E4–3333 Filed 11–23–04 8:45 am]

BILLING CODE 3510–DR–S

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board

AGENCY: Department of Defense.

ACTION: Notice of Advisory Committee meeting.

SUMMARY: The Defense Science Board Task Force on Force Protection in Urban and Unconventional Environments will meet in closed session on December 1–2, 2004, at Fort Irwin, CA; 29 Palms, CA; and March Air Reserve Base, CA. This Task Force will review and evaluate force protection capabilities in urban and unconventional environments and provide recommendations to effect change to the future Joint Force.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology & Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. Specifically, the Task Force's foci will be to evaluate force protection in the context of post major combat operations that have been conducted in Iraq and Afghanistan. In the operations, loss of national treasure—military and civilian, U.S. and other nations—has resulted from actions executed by non-state and rogue actors. The threat and capabilities these insurgent, terrorist and criminal actions present post a most serious challenge to our ability to achieve unified action.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App. 2), it has been determined that these Defense Science Board Task Force meetings concern matters listed in 5 U.S.C. 552b(c)(1) and that, accordingly, these meetings will be closed to the public.

Due to scheduling difficulties, there is insufficient time to provide timely notice required by Section 10(a)(2) of the Federal Advisory Committee Act and § 101–6.1015(b) of the GSA Final Rule on Federal Advisory Committee Management, 41 CFR Part 101–6, which further requires publication at least 15 calendar days prior to the meeting.

Dated: November 17, 2004.

Jeannette Owings-Ballard,

OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 04–25983 Filed 11–23–04; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Consolidation of Nuclear Operations Related to Production of Radioisotope Power Systems; Correction

AGENCY: Department of Energy.

ACTION: Notice of Intent; correction.

SUMMARY: The Department of Energy published a notice of intent in the **Federal Register** on November 16, 2004, (69 FR 67139) announcing its intent to prepare an environmental impact statement (EIS), for the proposed consolidation of nuclear activities related to production of radioisotope power systems required for Government national security and space exploration missions at a single, highly secure DOE site. The document contained an incorrect telephone number and an incorrect street address for a public meeting.

Corrections

In the **Federal Register** of November 16, 2004, in FR Doc. 04–25406, on page 67140, the following corrections should be made:

First column, first paragraph,

Twin Falls, ID: 1586 Blue Lakes Blvd. North,

Second column, under **ADDRESSES** heading, first paragraph,

You may leave a message at (800) 919–3706.

FOR FURTHER INFORMATION CONTACT: Timothy A. Frazier, Document Manager, NE–50/Germantown Building, Office of Space and Defense Power Systems, Office of Nuclear Energy, Science and Technology, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–1290, telephone 301–903–9420, or submitted via e-mail to *ConsolidationEIS@nuclear.energy.gov*.

Issued in Washington, DC on November 18, 2004.

Carol M. Borgstrom,

Director, Office of NEPA Policy and Compliance.

[FR Doc. 04–26035 Filed 11–23–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket Nos. PP 39–1 and PP–96–2]

Applications To Transfer Presidential Permits; Boise Cascade Corporation and Boise White Paper, LLC

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of applications.

SUMMARY: Boise Cascade Corporation (Boise) and Boise White Paper, L.L.C. (BWP) have jointly applied to transfer Presidential Permits PP–39 and PP–96 from Boise to BWP.

DATES: Comments, protests or requests to intervene must be submitted on or before December 27, 2004.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Import/Export (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202–586–9624 or Michael Skinker (Program Attorney) 202–586–2793.

SUPPLEMENTARY INFORMATION: The construction, operation, maintenance, and connection of facilities at the international border of the United States for the transmission of electric energy between the United States and a foreign country is prohibited in the absence of a Presidential permit issued pursuant to

Executive Order (EO) 10485, as amended by EO 12038. Existing Presidential permits are not transferable or assignable. However, in the event of a proposed voluntary transfer of physical facilities, in accordance with the regulations at 10 CFR 205.323, the existing holder of a permit and the transferee are required to a file joint application for transfer with the Department of Energy (DOE) that includes a statement of reasons for the transfer.

On November 7, 1966, the Federal Power Commission, the predecessor agency of the DOE, issued Presidential Permit PP–39 to Boise for a double circuit 6.6 kilovolt (kV) electrical transmission line (operated as a single circuit) that crosses the United States border with Canada at International Falls, Minnesota.

On July 7, 1994, DOE issued Presidential Permit PP–96, as amended, to Boise for a 115–kV electrical transmission line that crosses the United States border with Canada in the vicinity of International Falls, Minnesota. These facilities share the support structure with a 115–kV international transmission line owned and operated by Minnesota Power and authorized in Presidential Permit PP–78.

On November 1, 2004, Boise and BWP (collectively, the ''Applicants'') jointly filed an application with DOE to transfer Presidential Permits PP–39 and PP–96 from Boise to BWP. Boise and BWP have entered into a purchase and sale agreement that will result in Boise selling its Minnesota paper mill and electrical assets and exiting the paper business in Minnesota. BWP is a newly-formed holding company owned by Boise Cascade and will be a privately held company. In a supplemental filing in this docket on November 19, 2004, Boise notified DOE that the asset sale of the international transmission facilities was completed on October 29, 2004.

In these applications, the Applicants state that there will be no physical changes to the existing permitted facilities.

Procedural Matters: Any person desiring to become a party to these proceedings or to be heard by filing comments or protests to these applications should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the date listed above.

Comments on the joint applications to transfer Presidential Permit PP–39 or PP–96 from Boise to BWP should be clearly marked with Dockets PP–39–1 and PP–96–2. Dennis L. Radocha, Associate General Counsel, Boise Cascade Corporation, 1111 West Jefferson Road, P.O. Box 50, Boise, ID 83728; Brian R. Land, Esq., Kirkland & Ellis LLP, 655 Fifteenth Street, NW., Suite 1200, Washington, DC 20005; and Terry Ward, Vice President, Minnesota Operations, International Falls Paper Mill, Boise Paper Solutions, Boise Cascade Corporation, 400 Second Street, International Falls, MN 56649–2387.

Before a Presidential permit may be issued or amended, the DOE must determine that the proposed action(s) will not adversely impact on the reliability of the U.S. electric power supply system. In addition, DOE must consider the environmental impacts of the proposed action(s) pursuant to the National Environmental Policy Act of 1969. DOE also must obtain the concurrence of the Secretary of State and the Secretary of Defense before taking final action on a Presidential permit application.

Copies of these applications will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at *http://www.fe.doe.gov*. Upon reaching the Fossil Energy Home page, select ''Electricity Regulation,'' and then ''Pending Proceedings'' from the options menus.

Issued in Washington, DC, on November 18, 2004.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Fossil Energy.

[FR Doc. 04–26040 Filed 11–23–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Senior Executive Service; Performance Review Board

AGENCY: Department of Energy.

ACTION: SES Performance Review Board Standing Register.

SUMMARY: This notice provides the Performance Review Board Standing Register for the Department of Energy. This listing supersedes all previously published lists of PRB members.

DATES: These appointments are effective as of September 30, 2004.

Ackerly, Lawrence R, Allison, Jeffrey M., Anderson, Charles E., Anderson, Cynthia V., Anderson, Margot H., Angulo, Veronica A., Aoki, Steven NMN, Arkin, Richard W., Arthur III, William John, Ascanio, Xavier NMN, Ashworth, Dennis J.;

Baca, Frank A., Baca, Mark C., Bailey Jr., Lawrence O., Bajura, Rita A., Baker, Kenneth E., Barker Jr., William L., Bashista, John R., Bauer, Carl O., Beamon, Joseph A., Beard, Susan F., Beckett, Thomas H., Beecy, David J., Benneth, Ruth B., Beserra, Frank J., Bielan, Douglas J., Bieniawski, Andrew J., Black, Richard L., Black, Steven K., Blackwood, Edward B., Bladow, Joel K., Boardman, Karen L.;

Bonilla, Sarah J., Borchardt, Charles A., Borgstrom, Carol M., Borgstrom, Howard G., Bowman, Gerald C., Boyd, Gerald G., Braden Jr., Robert C., Bradley, Samuel M., Breznay, George B., Brodman, John R., Brody, Bruce A., Bromberg, Kenneth M., Bronstein, Eli B., Brown III, Robert J., Brown, Richard D., Brumley, William J., Bubar, Patrice M., Burgeson, Eric R., Burns, Allen L., Burrows, Charles W., Butler, Roger A.;

Callender, Brian W., Campbell, Elizabeth E., Campbell, James Thomas, Carabetta, Ralph A., Caravelli, John M., Cardinali, Henry A., Carlson, John T., Carlson, Kathleen Ann, Carnes, Bruce M., Cary, Steven V., Cavanagh, James J., Cerveny, Thelma J., Chacey, Kenneth A., Chalk, Steven G., Chung, Dae Y., Coburn, Leonard L., Cochran, Diane P., Cole, Almeda C., Combs, Marshall O., Conover, David W., Conti, John J., Cook, John S., Corey, Ray J., Costlow, Brian D., Craig Jr., Jack R., Crandall, David H., Crawford, David W., Cross, Claudia A., Cumesty, Edward G., Curtis, James H., Cygelman, Andre I.;

D'Agostino, Thomas Paul, Daugherty, Maurice W., Davies, Nelia A., Davis, Joseph H., De Alvarez, Alexis C., De Lorenzo, Ralph H., Decker, James F., Dedik, Patricia NMN, Dehmer, Patricia M., Dehoratiis Jr., Guido NMN,

Deihl, Michael A, Delwiche, Gregory K, Demko, Joseph C, Der, Victor K, Desmond Jr., William J, Dever, Gertrude L, Devito, Vincent NMN, Difiglio, Carmen NMN, Dixon, Robert K, Dobriansky, Larisa E, Dooley III, George J, Dyer, J Russell, Edmondson, John J, Egger, Mary H, Elwood, Jerry W, Erickson, Leif NMN, Errington, Gordon V, Esvelt, Terence G;

Faulkner, Douglas L, Fiore, James J, Fitzgerald, Cheryl P, Flanders, Douglass L, Foley, Kathleen Y, Fowler, Jennifer Johnson, Franklin, Charles Anson, Franklin, Rita R, Frazier, Marvin E, Frei, Mark W, Fresco, Maryann E, Fryberger, Teresa A, Fygi, Eric J;

Gale, Barry G, Garber, Janet L, Garland, Robert W, Garrish, Theodore J, Garson, Henry K, Gasperow, Lesley A, Gebus, George R, Gerrard, John E, Gibson Jr, William C, Gilbertson, Mark

A, Ginsberg, Mark B, Glenn, Daniel E, Golan, Paul M, Goldman, Peter R, Goldsmith, Robert NMN, Gollomp, Lawrence A, Goodman, Douglas NMN, Goodrum, William S, Gottlieb, Paul A, Greenberg, Raymone F, Greenwood, Johnnie D, Gresham, Larry M, Grose, Amy E, Gruenspecht, Howard K, Guevara, Arnold E, Gunn Jr, Marvin E;

Hacskaylo, Michael S, Hafner, Steven C, Hansen, Charles A, Hardin, Michael G, Hardwick Jr, Raymond J, Harmon, Harvey L, Harris, Robert J, Hartman, John R, Harvey, Tobin K, Hass, Rickey R, Hawthorne, Joan Gates, Hayward, Mary Alice, Headley, Larry C, Hefernan, Barbara J, Henneberger, Karen A, Hibbitts Jr, Howard D, Hickok, Steven G, Hill, David R, Hixon Jr, Harry W, Hodson, Patricia J, Holbrook, Phillip L, Holland, Michael D, Hollowell, Betty L N, Hood, Robert R, Hopf, Richard H, Huizenga, David G, Hunemuller, Maureen A, Hutto III, F Chase;

Izell, Kathy D, Jaffe, Harold NMN, Jenkins, Robert G, Johnson, Frederick M, Johnson, Milton D, Johnson, Robert Shane, Johnson, Sandra L, Johnston, Marc NMN, Jones, C Rick, Jones, Herbert M, Jordan, Robert R, Jordan, Rosalie M, Joseph, Antionette Grayso, Juarez, Liova D;

Kaempf, Douglas E, Kane, Michael C, Kennedy, John P, Kersten, John H, Keselburg, James D, Kight, Gene H, Kilpatrick, Michael A, Kirkendall, Nancy J, Kirkman, Larry D, Klein, Keith A, Knipp, Robert M, Knox, Eric K, Kolb, Ingrid A C;

Kolevar, Kevin M, Konopnicki, Thad T, Kotek, John F, Koury, John F, Kouts, Christopher A, Kovar, Dennis G, Krol, Joseph J, Kruger, Paul W, Kung, Huijou Harriet, Lambert, James B., Lange, Robert G, Lanthrum, J Gary, Lavine, Gary J, Lawrence, Andrew D, Lazor, John D, Lee, Steven NMN, Lehman, Daniel R, Lersten, Cynthia A, Lewis III, Charles B, Lewis Jr, William A, Lewis, Roger A, Lopatto, Jeanne T, Lowe, Owen W, Luczak, Joann H;

Maddox, Mark R, Magwood IV, William D Maharay, William S Male, Barbara D, Malinovsky, Joseph M, Malosh, George J, Mangeno, James J, Mann, Thomas O, Marcinowski III, Frank NMN, Markel Jr, Kenneth E, Marlay, Robert C, Marmolejos, Poli A, Martinez, Eloy Dennis, Masterson, Mary A, McCabe, Michael J, McCarty, Kathryn P, McCloud, Floyd R, McCormick, Matthew S, McCracken, Stephen H, McKee, Barbara N, McKenzie, John M, McMonigle, Joseph P, McMullan, Robert L, McRae, James Bennett, Meeks, Timothy J, Mellington, Suzanne P, Meyer, Charles E, Michelsen, Stephen J, Miller, Clarence L, Miller, Deborah C, Milner, Ronald A, Miotla, Dennis M;

Monette, Deborah D, Monhart, Jane L, Montano, Pedro A, Moorer, Richard F, Morrell, Paul Charles, Mortensen, Richard W, Mortenson, Victor A, Mosquera, James P, Mournighan, Stephen D, Mueller, Troy J, Murphie, William E, Naples, Elmer M, Nealy, Carson L, Newell, John D, Nolan, Elizabeth A, Norman, Paul E;

O'Brien, Betsy K, O'Fallon, John R, Olinger, Shirley J, Oliver, Lawrence R, Oliver, Stephen R, Olson, Dean G, Oosterman, Carl H, Osheim, Elizabeth L, Ott, Merrie Christine, Owen, Michael W, Owendoff, James M, Parkes, Rosita O, Parks Jr, William P, Parnes, Sanford J, Partinos, Aristides A, Pease, Harrison G, Penry, Judith M, Peterson, Bradley A, Piper II, Lloyd L, Podonsky, Glenn S, Powers, Kenneth W, Price Jr, Robert S, Provencher, Richard B, Przybylek, Charles S, Pumphrey, David L;

Rhoderick, Jay E, Richards, Stephen R, Richardson, Herbert NMN, Rispoli, James A, Roach, Randy A, Roberts, Michael NMN, Robinson, David M, Rodeheaver, Thomas N, Rodekohr, Mark E, Rodgers, Stephen J, Rodin, Laura M, Rollow, Thomas A. Rosen, Simon Peter, Rudings, George NMN, Russo, Frank B;

Ryder, Thomas S, Salm, Philip E, Salmon, Jeffrey T, Sato, Walter N, Schepens, Roy J, Schmitt, Eugene C, Schmitt, William A, Schnapp, Robert M, Schoenbauer, Martin J, Schweitzer, Eric A, Schwier, Jean F, Scott, Bruce B, Scott, Randal S, Sellers, Elizabeth D, Shages, John D, Sharpley, Christopher R, Shaw, John S, Shearer, C Russell H, Sheppard Jr, Franklin R, Sheppard, Catherine M, Sherman, Helen O;

Sigal, Jill L, Silbergleid, Steven A, Simpson, Christopher NMN, Simpson, Edward R, Singer, Marvin I, Siskin, Edward J, Sitzer, Scott B, Skubel, Stephen C, Slutz, James A, Smith, Alexandra B, Smith, Denise H, Smith, Kevin W, Snider, Linda J, Sohinki, Stephen M, Solich, Donald J, Spader, William F, Staffin, Robin NMN, Stallman, Robert M, Stark, Richard M, Stevens, Walter J, Stone, Barbara R, Stakey Jr, Joseph P, Strauss, Neal J, Sullivan, John R, Sutula, Raymond A, Swailes, John H, Swift, Justin R;

Taboas, Anibal L, Tavares, Antonio F, Taylor, Steve C, Taylor, William J, Tedrow, Richard T, Torkos, Thomas M, Trautman, Stephen J, Triay, Ines R, Turi, James A, Turner, James M, Underwood, William R, Vagts, Kenneth A, Valdez, William J, Vanzandt, Vickie A;

Wagner, M Patrice, Wahlquist, Earl J, Waisley, Sandra L, Wall, Edward James, Wallace, Terry L, Walsh, Robert J, Warnick, Walter L, Warther, Robert F, Weedall, Michael J, Weis, Michael J, Whitaker Jr, Mark B, Wieker, Thomas L, Wilcher, Larry D, Wilken, Daniel H, Wilkes, Bryan K, Williams, Alice C, Williams, Mark H, Willis, John W, Wilmot, Edwin L, Worthington, Patricia R, Wright, Stephen J, Wunderlich, Robert C, Yuan-Soo Hoo, Camille C, Zamorski, Michael J, Ziegler, Joseph D, Ziesing, Rolf F.

Issued in Washington, DC, November 18, 2004.

Claudia A. Cross,

Chief Human Capital Officer/Director, Office of Human Capital Management.

[FR Doc. 04–26036 Filed 11–23–04; 8:45 am]

BILLING CODE 6450–01–M

DEPARTMENT OF ENERGY

Senior Executive Service; Performance Review Board

AGENCY: Department of Energy.

ACTION: Notice of Designation of Performance Review Board Chair.

SUMMARY: This notice provides the Performance Review Board Chair designee for the Department of Energy: James T. Campbell.

DATES: This appointment is effective as of September 30, 2004.

Issued in Washington, DC November 18, 2004.

Claudia A. Cross,

Chief Human Capital Officer/Director, Office of Human Capital Management.

[FR Doc. 04–26037 Filed 11–23–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–69–000]

ANR Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

November 17, 2004.

Take notice that on November 12, 2004, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets, to become effective December 15, 2004:

Seventeenth Revised Sheet No. 2
Fifth Revised Sheet No. 193
Fourth Revised Sheet No. 194
Third Revised Sheet No. 195

ANR states that the purpose of the filing is to offer a tariff mechanism to resolve certain remaining issues relating to flowing volume commitments at ANR's Marshfield receipt point in Wood County, Wisconsin, as contemplated by the ANR's settlement with Viking Gas Transmission Company.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3326 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ES04–49–001]

California Independent System Operator Corporation; Notice of Filing

November 17, 2004.

Take notice that on November 12, 2004, California Independent System Operator Corporation (California ISO) amended its September 3, 2004 application submitted pursuant to section 204 of the Federal Power Act. The September 3, 2004 application sought authorization for California ISO to issue long-term debt in the form of bonds, notes and guarantees in an amount not to exceed $130 million. The amendment contains an ISO Governing Board resolution authorizing California ISO to proceed with the bond offering in an amount not to exceed $127 million.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on all the parties to this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. eastern time on November 26, 2004.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3321 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–43–001]

Dominion Cove Point LNG, LP; Notice of Tariff Filing

November 17, 2004.

Take notice that on November 10, 2004, Dominion Cove Point LNG, LP (Cove Point) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheet, to become effective December 27, 2004:

Substitute Fifth Revised Sheet No. 8

Cove Point states that this sheet is being filed to update the October 28, 2004, filing in this docket to be consistent with the correction proposed in Cove Point's November 4, 2004 errata filing in Docket Nos. CP01–76–010 and CP01–77–010.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3324 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP02–551–004]

Dominion Transmission, Inc.; Notice of Compliance Filing

November 17, 2004.

Take notice that on November 10, 2004, Dominion Transmission Inc. (DTI) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Tenth Revised Sheet No. 39, to be effective November 1, 2004.

DTI states that the purpose of this filing is to comply with the Letter Order issued in Docket No. RP02–551–003 on November 3, 2004. DTI states it is updating the penalty charges and retention amounts for Rate Schedules FT/FTNN, GSS, and ISS on Sheet No. 39 with the currently effective rates on Sheet Nos. 31, 32, and 35 of its tariff.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3322 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–362–002]

East Tennessee Natural Gas, LLC; Notice of Tariff Filing

November 17, 2004.

Take notice that on November 12, 2004, East Tennessee Natural Gas, LLC (East Tennessee) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following revised tariff sheets, to be effective July 1, 2004:

First Revised Sheet No. 176
First Revised Sheet No. 335
First Revised Sheet No. 393

East Tennessee states that the purpose of this filing is to reflect its corporate name change in tariff sheets that were pending before the Commission at the time East Tennessee submitted its name change filing on July 1, 2004, in the captioned docket. East Tennessee explains that the name chance was accepted by Commission orders issued subsequent to East Tennessee's name change filing.

East Tennessee states that copies of this filing have been served upon all affected customers of East Tennessee and interested state commissions, as well as upon all parties on the Commission's official service list in this proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3323 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ES04–46–002]

El Paso Electric Company; Notice of Filing

November 17, 2004.

Take notice that on November 16, 2004, El Paso Electric Company (El Paso) filed an application pursuant to section 204 of the Federal Power Act requesting that the Commission amend the authorization previously granted in ES04–46–000 to allow El Paso to extend the maturity date of the existing Series H Bonds to be consistent with the term of the revolving credit facility, and to authorize issuance of the additional $50 million of First Mortgage Bonds for the same period.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*.

Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. eastern time on November 26, 2004.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3329 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–68–000]

Maritimes & Northeast Pipeline, L.L.C.; Notice of Proposed Changes in FERC Gas Tariff

November 17, 2004.

Take notice that on November 12, 2004, Maritimes & Northeast Pipeline, L.L.C. (Maritimes) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, Second Revised Sheet No. 133, to become effective July 1, 2003.

Maritimes states that the purpose of this filing is to modify section 3.2(B) of Rate Schedule MNLFT to provide for the crediting of any usage charge outside tolerances amounts collected for deliveries that are less than 90% of a customer's scheduled quantity to those customers that did not incur such charges for the month in which such charges were collected.

Maritimes states that copies of its filing have been served upon all affected customers of Maritimes and interested state commissions.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3325 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–72–000]

Midwestern Gas Transmission Company; Notice of Proposed Changes in FERC Gas Tariff

November 18, 2004.

Take notice that on November 16, 2004, Midwestern Gas Transmission Company (Midwestern) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets to become effective December 16, 2004:

First Revised Sheet No. 79
Fifth Revised Sheet No. 246
Third Revised Sheet No. 110
Second Revised Sheet No. 251
Third Revised Sheet No. 111
First Revised Sheet No. 252
Fifth Revised Sheet No. 200
Second Revised Sheet No. 253
Sixth Revised Sheet No. 203
First Revised Sheet No. 267
Third Revised Sheet No. 205
Tenth Revised Sheet No. 273
Seventh Revised Sheet No. 206
Third Revised Sheet No. 400
Third Revised Sheet No. 233
Fourth Revised Sheet No. 401
Third Revised Sheet No. 235
Second Revised Sheet No. 402
Second Revised Sheet No. 236
Third Revised Sheet No. 403
First Revised Sheet No. 244
Fifth Revised Sheet No. 410

Midwestern states that the purpose of this filing is to (1) clarify portions of Midwestern's Rate Schedule SA and Supply Aggregation Service Agreement, (2) make certain changes to its General Terms and Conditions in its Tariff as a result of the issuance of Order No. 2004 and 3) make minor housekeeping changes.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed

docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E4–3312 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–176–105]

Natural Gas Pipeline Company of America; Notice of Negotiated Rate

November 17, 2004.

Take notice that on November 15, 2004, Natural Gas Pipeline Company of America (Natural) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheets, to become effective December 1, 2004:

Fifth Revised Sheet No. 26B
Second Revised Sheet No. 26B.01
First Revised Sheet No. 26B.02

Natural states that the purpose of this filing is to implement an extension to an existing negotiated rate transaction.

Natural states that copies of the filing are being mailed to all parties set out on the Commission's official service list in Docket No. RP99–176.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3320 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–70–000]

Northern Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

November 17, 2004.

Take notice that on November 15, 2004, Northern Natural Gas Company (Northern), tendered for filing in its FERC Gas Tariff, Fifth Revised Volume No. 1, Eighth Revised Sheet No. 66C, to be effective January 1, 2005.

Northern states that it is filing the above-referenced tariff sheets to provide eight non-conforming service agreements entered into between Northern and LSP–Whitewater Limited Partnership and LSP–Cottage Grove L.P.

Northern further states that copies of the filing have been mailed to each of its customers and interested State Commissions.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3327 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–71–000]

Sabine Pipe Line LLC; Notice of Proposed Changes in FERC Gas Tariff

November 17, 2004.

Take notice that on November 15, 2004, Sabine Pipe Line LLC tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, to become effective December 15, 2004:

First Revised Sheet No. 1
Third Revised Sheet No. 20
First Revised Sheet No. 21
First Revised Sheet No. 140

Sabine indicates that the purpose of this filing is to update Sabine's tariff by the removal of outdated material relating to Sabine's conversion from modified fixed variable rate design and Sabine's transition to unbundled service during its restructuring of services under FERC Order 636.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of

the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding.

Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3328 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–312–144]

Tennessee Gas Pipeline Company; Notice of Negotiated Rate

November 18, 2004.

Take notice that on November 15, 2004, Tennessee Pipeline Company (Tennessee) tendered for filing a negotiated rate arrangement between Tennessee and Coral Energy Resources, L.P. (Coral).

Tennessee requests that the negotiated rate arrangement between Tennessee and Coral become effective on December 1, 2004, if the Commission issues an order on or before November 19, 2004, otherwise, Tennessee requests that the negotiated rate arrangement become effective on January 1, 2005.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E4–3311 Filed 11–23–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Southwestern Power Administration

Integrated System Power Rates

AGENCY: Southwestern Power Administration, DOE.

ACTION: Notice of rate order.

SUMMARY: Pursuant to Delegation Order Nos. 00–037.00, effective December 6, 2001, and 00–001–00A, effective September 17, 2002, the Deputy Secretary has approved and placed into effect on an interim basis Rate Order No. SWPA–51, which increases the power rates for the Integrated System pursuant to the following Integrated System Rate Schedules:

Rate Schedule P–04, Wholesale Rates for Hydro Peaking Power

Rate Schedule NFTS–04, Wholesale Rates for Non-Federal Transmission/ Interconnection Facilities Service

Rate Schedule EE–04, Wholesale Rate for Excess Energy

The rate schedules supersede the existing rate schedules shown below:

Rate Schedule P–02, Wholesale Rates for Hydro Peaking Power—(superseded by P–04)

Rate Schedule NFTS–02, Wholesale Rates for Non-Federal Transmission/Interconnection Facilities Service— (superseded by NFTS–04)

Rate Schedule EE–02, Wholesale Rate for Excess Energy—(superseded by EE–04)

The effective period for the rate schedules specified in Rate Order No. SWPA–51 is January 1, 2005, through September 30, 2008.

FOR FURTHER INFORMATION CONTACT: Forrest E. Reeves, Assistant Administrator, Office of Corporate Operations, Southwestern Power Administration, Department of Energy, One West Third Street, Tulsa, Oklahoma 74103, (918) 595–6696, *gene.reeves@swpa.gov*.

SUPPLEMENTARY INFORMATION: Southwestern Power Administration's (Southwestern) Administrator has determined, based on the 2004 Integrated System Current Power Repayment Study, that existing rates will not satisfy cost recovery criteria specified in Department of Energy Order No. RA 6120.2 and Section 5 of the Flood Control Act of 1944. The finalized 2004 Integrated System Power Repayment Studies (PRSs), indicate that an increase in annual revenue of $8,576,164, or 7.5 percent, beginning January 1, 2005, will satisfy cost recovery criteria for the Integrated System projects. The proposed

Integrated System rate schedules would increase annual revenues from $114,973,800 to $123,549,964, primarily to recover increased expenditures in operations and maintenance (O&M) and investment. In addition, the PRS indicates the need for an annual increase of $737,300 in revenues received through the Purchased Power Adder to recover increased purchased energy costs. This rate proposal also includes a provision to continue the Administrator's Discretionary Purchased Power Adder Adjustment, to adjust the purchased power adder annually, of up to $0.0011 per kilowatthour as necessary, at his/her discretion, under a formula-type rate, with notification to the FERC.

The Administrator has followed Title 10, Part 903 Subpart A, of the Code of Federal Regulations, ''Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions'' in connection with the proposed rate schedule. On June 4, 2004, Southwestern published notice in the **Federal Register**, 69 FR 31608, of a 90-day comment period, together with a Public Information Forum and a Public Comment Form, to provide an opportunity for customers and other interested members of the public to review and comment on a proposed rate increase for the Integrated System. Both public forums were canceled since no one expressed an intention to participate. Written comments were accepted through September 2, 2005. Three comments were received and are addressed in this rate proposal.

Information regarding this rate proposal, including studies and other supporting material, is available for public review and comment in the offices of Southwestern Power Administration, Suite 1400, One West Third Street, Tulsa, Oklahoma 74103.

Following review of Southwestern's proposal within the Department of Energy, I approved, Rate Order No. SWPA–51, on an interim basis through September 30, 2008, which increases the existing Integrated System annual revenue requirement to $123,549,964 per year for the period January 1, 2005, through September 30, 2008.

Dated: November 16, 2004.

Kyle E. McSlarrow,

Deputy Secretary.

Order Confirming, Approving and Placing Increased Power Rate Schedules in effect on an Interim Basis

Pursuant to Sections 302(a) and 301(b) of the Department of Energy Organization Act, Public Law 95–91, the functions of the Secretary of the Interior and the Federal Power Commission under Section 5 of the Flood Control Act of 1944, 16 U.S.C. 825s, relating to the Southwestern Power Administration (Southwestern) were transferred to and vested in the Secretary of Energy. By Delegation Order No. 0204–108, effective December 14, 1983, the Secretary of Energy delegated to the Administrator of Southwestern the authority to develop power and transmission rates, delegated to the Deputy Secretary of the Department of Energy the authority to confirm, approve, and place in effect such rates on an interim basis and delegated to the Federal Energy Regulatory Commission (FERC) the authority to confirm and approve on a final basis or to disapprove rates developed by the Administrator under the delegation. Delegation Order No. 0204–108, as amended, was rescinded and subsequently replaced by Delegation Orders 00–037.00 (December 6, 2001) and 00–001–00A (September 17, 2002). The Deputy Secretary issued this rate order pursuant to said delegations.

Background

FERC confirmation and approval of the following Integrated System (System) rate schedules was provided in FERC Docket No. EF02–4011–000 issued October 22, 2003, for the period October 1, 2002, through September 30, 2006:

Rate Schedule P–02, Wholesale Rates for Hydro Peaking Power—(superseded by P–04)

Rate Schedule NFTS–02, Wholesale Rates for Non-Federal Transmission/Interconnection Facilities Service—(superseded by NFTS–04)

Rate Schedule EE–02, Wholesale Rate for Excess Energy—(superseded by EE–04)

Southwestern Power Administration's (Southwestern), Current Power Repayment Study (PRS) indicates that the existing rates will not satisfy present financial criteria regarding repayment of investment within a 50-year period due to cost adjustments to reflect the final cost allocation approval for the Harry S. Truman Project plus increasing operation and maintenance expenditures and investment for both the U.S. Army Corps of Engineers (Corps) and Southwestern. The revised PRS indicates that an increase in annual revenues of $8,576,164 is necessary beginning January 1, 2005, to accomplish repayment in the required number of years. Accordingly, Southwestern has prepared proposed rate schedules based on the additional revenue requirement and the 2004 Rate Design Study.

Informal meetings were held in April and May 2004 with customer representatives to review the repayment and rate design processes and present the basis for an approximately 8 percent annual revenue increase. In May 2004, Southwestern prepared a proposed 2004 PRS for the Integrated System.

Title 10, Part 903, Subpart A of the Code of Federal Regulations, ''Procedures for Public Participation in Power and Transmission Rate Adjustment,'' has been followed in connection with the proposed rate adjustments. More specifically, opportunities for public review and comment on proposed System power rates during a 90-day period were announced by notice published in the **Federal Register** June 4, 2004, (69 FR 31608). A Public Information Forum was scheduled for June 29, 2004, in Tulsa, Oklahoma, and a Public Comment Forum was scheduled for July 27, 2004, also in Tulsa. Both were canceled since no one expressed an intention to attend. Written comments were due by September 2, 2004. Southwestern mailed copies of the proposed May 2004 PRS and Rate Design Studies to customers and interested parties that requested the data, for review and comment during the formal period of public participation.

Following conclusion of the comment period on September 2, 2004, comments presented during the formal public participation process were reviewed. Once all comments were carefully evaluated and responded to, the 2004 PRS and Rate Design Studies were completed. Changes were made to the 2004 PRS to reflect final audited financial data for FY 2003 and to reflect refinements in cost estimates. The studies were finalized in September 2004. The Administrator decided to submit the rate proposal for interim approval and implementation. The comments resulting from the public participation process and responses, as developed by Southwestern's staff, are contained in this Rate Order.

Discussion

General

The existing rate schedules developed in the 2002 Integrated System PRS were the basis for revenue determination in the September 2004 Integrated System Current PRS. The Current PRS indicates that existing rates are insufficient to produce the annual revenues necessary to accomplish repayment of the capital investment as required by Section 5 of

the Flood Control Act of 1944 and Department of Energy (DOE) Order No. RA 6120.2.

A Revised PRS was prepared based on $8,576,164 of additional annual revenue beginning January 1, 2005, to satisfy repayment criteria.

In Southwestern's 2004 Rate Proposal, two noteworthy issues are described in detail. The issues are: (1) the final approval of the Harry S. Truman (Truman) project cost allocation, and (2) the rate design procedures for implementing the revenue increase.

Harry S. Truman Final Cost Allocation

The final approval of the Truman cost allocation was issued by the Corps on May 3, 2003. Estimates for the cost allocation adjustments are included in this PRS. The Corps will make adjustments to Operation and Maintenance Expenses, Interest and Investment to reflect the change in joint-use percentages. The Corps has indicated that adjustments will be made to the Corps' FY 2004 power reports and reflected on their FY 2004 financial statements, which will be reviewed and certified by the auditors. The adjustments will then be included in the historical actual data in the 2005 PRS.

Change to Rate Design Procedures

Several customers requested Southwestern to consider assigning the revenue increase to the peaking energy rate in lieu of the capacity rate. This alternative was requested to help some customers pass on the increased costs from Southwestern as a fuel cost adjustment to their customers without the need for a formal rate increase. Southwestern presented proposed alternative rate designs that might meet the customers' needs, while at the same time meeting Southwestern's repayment requirements together with the most recent rate design process. The customers that attended a meeting at which Southwestern made this presentation reached a consensus that they would prefer that Southwestern submit the rate design incorporating the changes in the energy rate in the proposed rate filing. The change in the rate design resulted in little, if any, impact on customers as compared with the most recent rate design process.

Rates were designed to recover the additional revenue requirements. The monthly demand charge for the sale of Federal hydroelectric power has increased. The energy charge was separated into a peaking energy charge and a supplemental energy charge, both of which reflected increases over the current base energy rate. The transformation charge, though paid by a few customers having 69 kV and below deliveries, has increased and affects revenues as well. In addition, transmission charges for non-Federal, firm service have increased. The increases to both transformation and transmission charges are due to including projected additions and replacements to Southwestern's aging transmission facilities since the last rate change.

In accordance with FERC's Order No. 888, Southwestern will continue charging separately for five ancillary services and offering network transmission service.

In accordance with FERC's Order No. 888, Southwestern will continue charging separately for five ancillary services and offering network transmission service. Southwestern's rate design has separated the five ancillary services for all transmission service. Two ancillary services, Scheduling, System Control and Dispatch Service together with Reactive and Voltage Support Service, are required for every transmission transaction. These charges are also a part of the capacity rate for Federal power. This is consistent with Southwestern's long-standing practice of charging for the sale and delivery of Federal power in its Federal demand charge. The three remaining ancillary services will be made available to any transmission user within Southwestern's control area, including Federal power customers. The rate schedules for Peaking Power and Non-Federal Transmission Service reflect these charges. Network transmission service is provided to those, also within Southwestern's control area, who request the service, but for non-Federal deliveries only, and who contracted with Southwestern for this service prior to the Southwest Power Pool offering Network Service. The rate for and application of this service are identified in the Non-Federal Transmission/ Interconnection Facilities Service Rate Schedule, NFTS–04.

With respect to the Purchased Power Adder (Adder), Southwestern is proposing, as in all previous proposals beginning with the 1983 implementation of the purchased power rate component, that the Adder be set equal to the current average long-term purchased power rate requirement. As shown in the Rate Design Study, the amount is determined by dividing the estimated total average direct purchased power costs by Southwestern's total annual contractual 1200-hour peaking energy commitments to the customers (exclusive of contract support arrangements). In this rate proposal, the resulting Adder is $0.0028 per kWh of peaking energy. The total revenue created through application of this Adder would enable Southwestern to cover its average annual purchased power costs.

Comments and Responses

The Southwestern Power Administration (Southwestern) responded to numerous questions to which responses were provided during the public participation period which are included in the background information. In addition, Southwestern received comments from three entities during the public participation process. Those comments and Southwestern's responses are summarized into five general areas of concern, and are as follows:

Control Costs

Comments

Southwestern and the Corps should schedule future needed work so as not to cause a rate increase by doing all the work in the same fiscal year. The commenter suggests that the big projects be leveled out over time to achieve this end.

Response

Southwestern agrees with the commenter and will make every effort to assure that its forecasts of future needed work represent what Southwestern will be able to achieve in a particular year. Southwestern has coordinated future Corps activities with a joint Corps/ Southwestern/Customer Group to assure that the Corps levels out its large projects, if practical, and includes in each year's projections no more than what it believes it will be able to accomplish in that year. Balancing the need to ensure that the hydroelectric facilities are in good serviceable condition and the cost of keeping those facilities in that condition is an on-going concern continually monitored by the two agencies. Southwestern supports performance of large maintenance efforts in phases where feasible. Further, by the nature of the power repayment study process, large project costs incurred in any year (except the last year of the Cost Evaluation Period (CEP)) would have little effect on the need for a rate increase. Southwestern is careful to avoid incorporating such cost variations in the last year of the CEP.

Unfunded Retirement, Health, and Life Insurance Benefits

Comments

One commenter acknowledges that inclusion of ''unfunded'' Civil Service

Retirement System (CSRS)/Health/Life Insurance Benefits as a cost in Southwestern's rates was raised in Southwestern's 2002 rate case before the FERC. However, the commenter states that they will continue to raise this issue until all federal agencies that are self-supporting pay for these future funding shortfalls in the same manner as the Power Marketing Administrations. Another commenter does not oppose the inclusion of ''unfunded'' CSRS costs in the rates, but believes that Southwestern should: (1) Properly account for the additional interest effects of the revenues collected for future retirements; (2) credit Southwestern's balance to be repaid with compounded interest from the collected funds; and (3) not repay investments without consideration of customer deposits.

Response

The Federal Accounting Standards Advisory Board issued Statement of Federal Financial Accounting Standards (SFFAS) #5 (September 1995) which provides guidance on how to determine and handle accounting treatment of these post retirement costs. In FY1998 Southwestern began recording values for the post retirement benefits, based on cost factors provided by the Office of Personnel Management (OPM). OPM provides, annually, cost factors for computing these unfunded post retirement expenses in three areas; pensions, health insurance and life insurance.

OPM's actuarial calculations are based in large measure on its assumptions about the future. Both economic (inflation, interest rates, and future salary levels) and demographic (*e.g.*, rates of retirement, mortality, and separation) assumptions are included in the calculations.

SFFAS #5 (paragraph 59) states, ''For pension and other retirement benefits, the expense is recognized at the time the employees' services are rendered.''

SFFAS #5 (paragraph 74) states, ''The Federal employer entity should recognize a pension expense in its financial report that equals the service cost. Service cost is defined as the actuarial present value of benefits attributed by the pension plan's benefit formula to services rendered by employees during an accounting period. The term is synonymous with normal cost.''

Financial Accounting Standards Interpretation Number 4; Accounting for Pension Payments in Excess of Pension Expense: Changes in normal costs due to re-estimates of demographic and economic assumptions should be accounted for by the recording entity. The effect of the change should be recognized in current and future years.

OPM takes an annual snap shot of what the normal cost would be to determine the uncaptured (unfunded) post retirement costs. This process involves a review of actuarial data for both retirees and current employees, with the retirement cost factor only being applied to current Federal employees in the CSRS retirement system. The unfunded amounts for health and life apply to all current employees.

This post retirement cost is an annual cost of operations and is recorded as part of each agency's annual operation and maintenance cost. It is not an expense deferred to a future period, as Paragraph 59 of SAFFAS #5 clearly defines it as a current year cost. It is recorded as such in Southwestern's financial records.

Southwestern agrees with the comment that it should properly account for the additional interest effects of the revenues collected and believes that we are currently doing so. As stated in the 2002 Integrated System rate case, Southwestern's existing procedure imputes an interest credit at current year interest rates on all revenues received—which would include revenues received to repay CSRS costs. The effect of the interest credit carries throughout the entire repayment period. Likewise, annual costs, such as the unfunded costs at issue here, will also incur an interest charge. Regarding the issue of applying revenues received for CSRS expenses to Southwestern's debt, the application of revenues is specified by DOE Order 6120.2 (paragraph 8c(3)) which states ''Annual revenues will be first applied to the following recovery of costs during the year in which they occurred: operation and maintenance (O&M), purchased and exchanged power, transmission service and other, and interest expense and any appropriation amortization of revenue bonds. Remaining revenues are available for amortization * * *'' Therefore, Southwestern applies its revenues received to cover the CSRS expenses (a current year cost) before it applies any revenue toward the amortization of the Federal investment.

Increased Corps O&M Expenses

Comments

Commenters state that the Corps' expenses continue to spiral upward annually—unchecked and that Southwestern should obtain information from the Corps that would support the projected O&M expenses, not just rely on unexplained assurances that the O&M is justified.

Response

Projections for Corps O&M are developed by the Corps and provided to Southwestern annually. The Corps makes projections of its base O&M costs using historical information and planning documents, and also includes projections for large maintenance items for each of the projects that they expect to complete. These projections are made in current year dollars and do not include inflation. Southwestern reviews this information, questioning the Corps where inconsistencies seem to occur, clarifying its understanding of the cost estimates, and adjusting the estimates to future year dollars based on the Gross Domestic Product Index to incorporate inflationary expectations.

The Corps' base O&M expenses are largely related to salaries. During recent years, all Federal employees have received approximately a 4 percent increase in salaries annually, together with the increased costs of benefits incurred for these employees. These personnel costs are included in the base estimates for O&M. These base estimates, together with the large maintenance items have resulted in actual increased O&M costs for the Corps. Although the Corps has historically, in total, been fairly accurate, its projections for O&M costs for the past four years have been less than what was recorded as expended on its financial statements. The Corps has confirmed that the past few years' projections were based on anticipated reductions in funding, but realized it was underestimating and has been increasing its estimates to better reflect its expected expenditures. Southwestern agrees with the Corps that the increased estimates of O&M costs better reflect its expenditures. The Corps' O&M costs are not anticipated to decrease so long as all phases of project rehabilitations and a backlog of maintenance remain to be completed on the projects.

Southwestern has no oversight authority with regard to Corps expenditures for O&M activities, but is responsible for repaying the Corps' power-related costs pursuant to the Flood Control Act of 1944. The Corps is responsible for managing their organization. Southwestern agrees that such costs should be prudently and timely incurred at reasonable levels consistent with sound business principles. Southwestern has inquired further of the Corps and has been advised that the Corps believes that its FY 2004 O&M estimates fairly represent

the minimum expenditure level expected for the projects' O&M and that this level of expenditure is expected to be reflected on its financial statements. The Corps believes that its internal controls, accounting system reviews, audits and funding procedures effectively provide the needed level of justification, consistency and control of its O&M expenditures.

Isolated Projects and Bundled Rates

Comment

One Commenter stated the belief that the customers who take power from Narrows, Denison and Whitney pay bundled rates, without receiving any benefit from Southwestern's transmission system. These customers pay other providers for the same services and should receive a credit from Southwestern for incurring the extra costs that a typical Southwestern customer does not pay. These customers agree with paying Southwestern for the services they receive, but do not believe they should be paying for transmission and ancillary services that they do not use. In addition, they believe they should receive credit for incurring costs that the typical Southwestern customer does not.

Response

Southwestern's position on this issue has not changed from its 1997 and 2002 Integrated System rate package responses. Southwestern's sales of Federal power and energy are based on a ''postage-stamp'' type rate, which is based on the financial integration of all the projects marketed under the Integrated System, as well as various components of Southwestern's transmission system. The capacity rate for all Federal power customers includes a transmission component and the two required ancillary services. The transmission component of this rate has been set to assure that Southwestern charges itself the same rates it charges for the use of the transmission system for wheeling non-Federal power.

The customers who receive the total output of specific Corps projects that are presently electrically isolated from Southwestern's primary interconnected system requested, at the time of their contract renewal, financial integration of such projects into the Integrated System to receive certain benefits, including lower costs. Such customers receive a number of benefits from their project purchases that other Federal customers do not, such as overload capacity, condensing, greater scheduling flexibility, and an exclusion from paying the Purchased Power Adder because of their obligation to meet Southwestern's 1200 hour minimum delivery requirement. Such projects also include components of Southwestern's transmission system and switchyard facilities used to deliver power and energy from the dams, and the costs of such facilities are recovered under the Integrated System rates. Revenues from all sales within the Integrated System are applied toward repayment of all Federal investment for all projects, regardless of their electrical integration status.

Southwestern is not required by FERC Order No. 888 or Order No. 2000 to offer unbundled services to its customers. Section 5 of the Flood Control Act of 1944 sets forth the statutory requirements for the sale and delivery of Federal power and energy. Furthermore, based on DOE policy, ''each of the PMAs that own transmission facilities will publish generally applicable open access wholesale transmission tariffs and will take service itself under such tariffs. The tariffs will include rates, terms, and conditions, and will offer transmission services, including ancillary services, to all entities eligible to seek a transmission order under section 211 of the Federal Power Act * * *'' Southwestern has complied with this policy in separating its non-Federal transmission service and to provide for ancillary services.

There is no overriding factor that compels Southwestern to change its previous determination that those customers who are presently electrically isolated from Southwestern's primary interconnected system do, in fact, derive benefit from the projects themselves and the transmission system and related facilities, and the power rate charged to the customers reflects such benefits. The parties expressing these concerns voluntarily and knowingly entered into long-term contractual arrangements to receive the benefits of these projects at integrated system rates. Based on prior FERC orders, we believe it is inappropriate for the parties again to seek, through the rate development process, to overturn what was done by their request and for their benefit through mutually agreeable bilateral contracts.

Alternative Rate Design

Comment

A commenter has stated that an alternative rate design was adopted by Southwestern without informed customer input.

Response

Several customers asked Southwestern to consider assigning the 2004 Integrated System revenue increase to the peaking energy rate in lieu of the capacity rate. The requested action was intended to help some customers pass on the increased costs from Southwestern through their fuel cost adjustments without having to formally increase their rates. Southwestern presented proposed alternative rate designs that might meet the customers' needs and at the same time meet Southwestern's repayment requirements, together with the most recent rate design process, at a special meeting held several weeks after the request. Many of the customers and a representative of the commenter were in attendance. The attendees reached a consensus that they would prefer that Southwestern submit the alternative rate design currently in the proposed rate filing. All customers and interested parties had a formal 90-day public comment period in which to review the proposed rate filing and provide comments. Only one commenter expressed any opposition to the proposed rate design based on the increased costs to them. Several customers verbally indicated their appreciation of the consideration of the customer request by Southwestern.

Because of the commenter's concern regarding increased costs to customers as a result of the proposed rate design, Southwestern reviewed the proposed rate design and determined that in separating the base energy rate between peaking energy and supplemental energy, some of the costs associated with the supplemental energy rate were incorrectly assigned to the peaking energy rate. As a result, the rates were adjusted to more accurately reflect the appropriate cost assignment. Southwestern then estimated the financial impacts to the customers and determined that the currently proposed rate design will meet Southwestern's repayment requirements and not cost the customers and, in particular, the commenter, any more than what it would have cost them under the previous rate design.

Other Issues

Other issues are discussed in the Administrator's Record of Decision.

Availability of Information

Information regarding this rate proposal, including studies, comments and other supporting material, is available for public review and comment in the offices of Southwestern

Power Administration, One West Third Street, Tulsa, OK 74101.

Administrator's Certification

The September 2004 Revised Power Repayment Study indicates that the increased power rates will repay all costs of the Integrated System including amortization of the power investment consistent with the provisions of Department of Energy Order No. RA 6120.2. In accordance with Delegation Order No. 00–037.00, December 6, 2001, and Section 5 of the Flood Control Act of 1944, the Administrator has determined that the proposed System rates are consistent with applicable law and the lowest possible rates consistent with sound business principles.

Environment

The environmental impact of the proposed System rates was evaluated in consideration of DOE's guidelines for implementing the procedural provisions of the National Environmental Policy Act and was determined to fall within the class of actions that are categorically excluded from the requirements of preparing either an Environmental Impact Statement or an Environmental Assessment.

Order

In view of the foregoing and pursuant to the authority delegated to me the Deputy Secretary of Energy, I hereby confirm, approve and place in effect on an interim basis, effective January 1, 2005, the following Southwestern Integrated System Rate Schedules, which shall remain in effect on an interim basis through September 30, 2008, or until the FERC confirms and approves the rates on a final basis.

Dated: November 6, 2004.

Kyle E. McSlarrow,

Deputy Secretary.

[FR Doc. 04–26039 Filed 11–23–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Southwestern Power Administration

Sam Rayburn Dam Power Rate Schedules

AGENCY: Southwestern Power Administration, DOE.

ACTION: Notice of rate order.

SUMMARY: Pursuant to Delegation Order Nos. 00–037.00, effective December 6, 2001, and 00–001.00A, effective September 17, 2002, the Deputy Secretary has approved and placed into effect on an interim basis Rate Order No. SWPA–52, which increases the power rate for the Sam Rayburn Dam Project (Rayburn) pursuant to the following Sam Rayburn Dam Rate Schedule:

Rate Schedule SRD–04, Wholesale Rates for Hydro Power and Energy Sold to Sam Rayburn Dam Electric Cooperative, Inc., (Contract No. DE–PM75–92SW00215)

The effective period for the rate schedule specified in Rate Order No. SWPA–52 is January 1, 2005, through September 30, 2008.

FOR FURTHER INFORMATION CONTACT: Mr. Forrest E. Reeves, Assistant Administrator, Office of Corporate Operations, Southwestern Power Administration, Department of Energy, One West Third Street, Tulsa, Oklahoma 74103, (918) 595–6696, *gene.reeves@swpa.gov*.

SUPPLEMENTARY INFORMATION: The existing hydroelectric power rate for the Rayburn project is $2,013,024 per year. The rate was approved on a final basis by the Federal Energy Regulatory Commission on January 31, 2003, for the period October 1, 2002, through September 30, 2006. The 2004 Rayburn Power Repayment Studies indicate the need for an increase in the annual rate of $500,676, or 24.9 percent beginning January 1, 2005.

The Administrator, Southwestern Power Administration (Southwestern) has followed Title 10, Part 903 Subpart A, of the Code of Federal Regulations, ''Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions'' (Part 903) in connection with the proposed rate schedule. On July 21, 2004, Southwestern published notice in the **Federal Register**, 69 FR 43580, of a 90-day comment period, together with a Public Information Forum and a Public Comment Forum, to provide an opportunity for customers and other interested members of the public to review and comment on a proposed rate increase for the Rayburn project. Both public forums were canceled when no one expressed an intention to participate. Written comments were accepted through October 19, 2004. One comment was received from Gillis & Angley, Counsellors at Law, on behalf of Sam Rayburn Municipal Power Agency and Vinton Public Power Authority, (organizations within Sam Rayburn Dam Electric Cooperative, Inc.) which stated that they had no objection to the proposed rate adjustment.

Information regarding this rate proposal, including studies and other supporting material, is available for public review and comment in the offices of Southwestern Power Administration, One West Third Street, Tulsa, Oklahoma 74103.

Following review of Southwestern's proposal within the Department of Energy, I approved Rate Order No. SWPA–52, on an interim basis, which increases the existing Rayburn rate to $2,513,700, per year, for the period January 1, 2005, through September 30, 2008.

Dated: November 16, 2004.

Kyle E. McSlarrow,

Deputy Secretary.

[Rate Order No. SWPA–52]

Order Confirming, Approving and Placing Increased Power Rate Schedule in Effect on an Interim Basis

Pursuant to Sections 302(a) and 301(b) of the Department of Energy Organization Act, Pub. L. 95–91, the functions of the Secretary of the Interior and the Federal Power Commission under Section 5 of the Flood Control Act of 1944, 16 U.S.C. 825s, relating to the Southwestern Power Administration (Southwestern) were transferred to and vested in the Secretary of Energy. By Delegation Order No. 0204–108, effective December 14, 1983, the Secretary of Energy delegated to the Administrator of Southwestern the authority to develop power and transmission rates, delegated to the Deputy Secretary of the Department of Energy the authority to confirm, approve, and place in effect such rates on an interim basis and delegated to the Federal Energy Regulatory Commission (FERC) the authority to confirm and approve on a final basis or to disapprove rates developed by the Administrator under the delegation. Delegation Order No. 0204–108, as amended, was rescinded and subsequently replaced by Delegation Orders 00–037.00 (December 6, 2001) and 00–001–00A (September 17, 2002). The Deputy Secretary issued this rate order pursuant to said delegations.

Background

The Sam Rayburn Dam Project (Rayburn) is located on the Angelina River in the State of Texas in the Neches River Basin. Since the beginning of its operation in 1965, it has been marketed as an isolated project, under contract with Sam Rayburn Dam Electric Cooperative, Inc. (Contract No. DE–PM75–92SW00215).

In the FERC Docket No. EF03–4021–000, issued January 31, 2003, for the period October 1, 2002, through September 30, 2006, the FERC confirmed and approved the current annual Sam Rayburn Dam rate of $2,013,024.

Discussion

Southwestern's 2004 Current Power Repayment Study (PRS) indicates that the existing annual power rate of $2,013,024 does not represent the lowest possible rate needed to meet cost recovery criteria. The increased revenue requirement is due to an increase in the U. S. Army Corps of Engineers (Corps) operations and maintenance expense estimates. The Revised PRS indicates that an increase in annual revenues of $500,676 beginning January 1, 2005, is sufficient to accomplish repayment of the Federal investment in the required number of years. Accordingly, Southwestern developed a proposed rate schedule based on that increased revenue requirement.

Title 10, Part 903, Subpart A of the Code of Federal Regulations, ''Procedures for Public Participation in Power and Transmission Rate Adjustment,'' has been followed in connection with the proposed rate adjustment. More specifically, opportunities for public review and comment during a 90-day period on the proposed Rayburn power rate were announced by notice published in the **Federal Register**, July 21, 2004, 69 FR 43580. A Public Information Forum was scheduled to be held July 27, 2004, and a Public Comment Forum was scheduled to be held August 26, 2004, both in Tulsa, Oklahoma. Both forums were canceled as no one expressed an intent to participate. Written comments were due by October 19, 2004. Southwestern provided the **Federal Register** notice, together with supporting data, to the customer and interested parties for review and comment during the formal period of public participation. In addition, prior to the formal 90-day public participation process, Southwestern discussed with the customer representatives the preliminary information on the proposed rate adjustment. Only one formal comment was received from Gillis & Angley, Counsellors at Law, on behalf of Sam Rayburn Municipal Power Agency and Vinton Public Power Authority, (organizations within Sam Rayburn Dam Electric Cooperative, Inc.) which stated that they had no objection to the proposed rate adjustment.

Upon conclusion of the comment period in October 2004, Southwestern finalized the PRS and rate schedule for the proposed annual rate of $2,513,700 which is the lowest possible rate needed to satisfy repayment criteria. This rate represents an annual increase of 24.9 percent.

Availability of Information

Information regarding this rate increase, including studies and other supporting material, is available for public review and comment in the offices of Southwestern Power Administration, One West Third Street, Tulsa, Oklahoma 74103.

Comments and Responses

Southwestern received one written comment in which customer representatives expressed no objection to the proposed rate adjustment.

Other Issues

There were no other issues raised during the informal meeting or during the formal public participation period.

Administrator's Certification

The 2004 Revised Rayburn PRS indicates that the annual power rate of $2,513,700 will repay all costs of the project, including amortization of the power investment consistent with provisions of the Department of Energy (DOE) Order No. RA 6120.2. In accordance with Delegation Order Nos. 00–037.00 (December 6, 2001) and 00–001.00A (September 17, 2002), and Section 5 of the Flood Control Act of 1944, the Administrator has determined that the proposed Rayburn power rate is consistent with applicable law and the lowest possible rate consistent with sound business principles.

Environment

The environmental impact of the rate increase proposal was evaluated in consideration of DOE's guidelines for implementing the procedural provisions of the National Environmental Policy Act, 10 CFR 1021, and was determined to fall within the class of actions that are categorically excluded from the requirements of preparing either an Environmental Impact Statement or an Environmental Assessment.

Order

In view of the foregoing and pursuant to the authority delegated to me, I hereby confirm, approve and place in effect on an interim basis, for the period January 1, 2005, through September 30, 2008, the annual Sam Rayburn Dam Rate of $2,513,700 for the sale of power and energy from Sam Rayburn Dam to the Sam Rayburn Dam Electric Cooperative, Inc., under Contract No. DE–PM75–92SW00215, dated October 7, 1992. This rate shall remain in effect on an interim basis through September 30, 2008, or until the FERC confirms and approves the rate on a final basis.

Dated: November 16, 2004.

Kyle E. McSlarrow,

Deputy Secretary.

[FR Doc. 04–26038 Filed 11–23–04; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[SFUND–2004–0010; FRL–7840–9]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Application for Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases Under CERCLA Section 123 (Renewal), EPA ICR Number 1425.06, OMB Control Number 2050–0077

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on 11/30/04. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number SFUND–2004–0010, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *Superfund.docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Superfund Docket, Mail Code 5202T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Lisa Boynton, Office of Emergency Management, Mail Code 5204G, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–603–

9052; fax number: 703–603–9104; e-mail address: *boynton.lisa@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 10th, 2004, (69 FR 48490), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. SFUND–2004–0010, which is available for public viewing in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744 and the telephone number for the Superfund Docket is (202) 566–0276 (*http://www.epa.gov/edocket*). An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket*. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket*.

Title: Application for Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases Under CERCLA Section 123 (Renewal).

Abstract: The Agency requires applicants for reimbursement under this program authorized under section 123 of CERCLA to submit an application that demonstrates consistency with program eligibility requirements. This is necessary to ensure proper use of the Superfund. EPA reviews the information to ensure compliance with all statutory and program requirements. The applicants are local governments who have incurred expenses, above and beyond their budgets, for hazardous substance response. Submission of this information is voluntary and to the applicant's benefit.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 9 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Various units of local governments.

Estimated Number of Respondents: 200/year.

Frequency of Response: Occasional, only if respondent wishes reimbursement.

Estimated Total Annual Hour Burden: 1,800 hours.

Estimated Total Annualized Cost Burden: $33,300, which includes $0 Capital expenditure/Startup costs, $0 O&M costs, and $ 33,300 Respondent Labor costs.

Changes in the Estimates: There is no change.

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26072 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2004–0089, FRL–7841–1]

Agency Information Collection Activities: Proposed Collection; Comment Request; Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses (Renewal); EPA ICR Number 1702.04, OMB Control Number 2060–0302

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on November 30, 2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OAR–2004–0089, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *a-and-r-docket@epa.gov*, or by mail to: Environmental Protection Agency, EPA Docket Center (EPA/DC), Air and Radiation Docket and Information Center, Mail Code 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Ms. Nydia Y. Reyes-Morales, Mail Code 6403J, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 343–9264; fax number: (202) 343–2804; e-mail address: *reyes-morales.nydia@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On July 20, 2004 (69 FR 43411), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID number OAR–2004–0089, which is available for public viewing at the Air and Radiation Docket, in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Retrofit/Rebuild Requirements for 1993 and Earlier Model Year Urban Buses (40 CFR Part 85, Subpart O) (Renewal).

Abstract: Section 219(d) of the Clean Air Act, as amended in 1990, required that the EPA promulgate regulations for urban buses that: (a) Operate in Metropolitan Statistical Areas (MSA) or consolidated MSA's with a 1980 population of 750,000 or more; (b) are not subject to the 1994 or later urban bus standards; and (c) have their engines replaced or rebuilt after January 1, 1995. The CAA Amendments require the subject urban buses be retrofitted to comply with an emission standard that reflects the best retrofit technology and maintenance practices reasonably achievable. Under these provisions, EPA set requirements for pre-1994 model year urban buses when urban bus engines are rebuilt or replaced. The program requires that the particulate emissions level of the urban bus engines be reduced to a level below the engines' original particulate level through the use of retrofit/rebuild equipment that is certified by EPA. The program will phase itself out as pre-1994 urban buses are retired from fleets. Responses to the collection of information are mandatory. All the information required by this collection is needed for the implementation and the activities of various EPA programs. The information is collected by the Engine Programs Group, Certification and Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation. Specific certification information submitted by manufacturers is held as confidential. Confidentiality of proprietary information is granted in accordance with the Freedom of Information Act, EPA regulations at 40 CFR part 2, and class determinations issued by EPA's Office of General Counsel.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 129 hours per retrofit equipment manufacturer and 33 hours per bus operator. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Entities potentially affected by this action are manufacturers of retrofit equipment and urban bus fleet operators.

Estimated Number of Respondents: 41.

Frequency of Response: Annually and on occasion.

Estimated Total Annual Hour Burden: 1,457.

Estimated Total Annual Cost: $186,148, which includes $0 annualized capital/startup costs, $111,401 annual O&M costs, and $74,747 annual labor costs.

Changes in the Estimates: There is a decrease of 2,252 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is due to changes in the estimated number of respondents. The decrease in burden is, therefore, due to an adjustment to the estimates.

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26073 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[RCRA–2004–0005; FRL–7841–2]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Requirements and Exemptions for Specific RCRA Wastes (Renewal), EPA ICR Number 1597.06, OMB Control Number 2050–0145

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to

expire on November 30, 2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number RCRA–2004–0005, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *RCRA-docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Resource Conservation and Recovery Act (RCRA) Docket, Mail Code 5305T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Tab Tesnau, Office of Solid Waste, Mail Code 5302W, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–605–0636; fax number: 703–308–8617; e-mail address: *tesnau.tab@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On April 26, 2004 (69 FR 22507), EPA sought comments on the ''Storage, Treatment, and Disposal of Mixed Waste'' ICR, and on June 25, 2004 (69 FR 35594), EPA sought comments on the ''Reporting and Recordkeeping Requirements for Universal Waste Handlers and Destination Facilities'' ICR pursuant to 5 CFR 1320.8(d). EPA received no comments to either notice.

EPA has established a public docket for this ICR under Docket ID No. RCRA–2004–0005, which is available for public viewing at the RCRA Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket*. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket*.

Title: Requirements and Exemptions for Specific RCRA Wastes (Renewal).

Abstract: In the 1976 Resource Conservation and Recovery Act (RCRA), as amended, Congress directs the U.S. Environmental Protection Agency (EPA) to develop and administer a comprehensive program for the safe management and disposal of hazardous waste. In 1980, EPA promulgated regulations in 40 CFR part 261–265 to comply with RCRA. EPA has since added to these regulations on many occasions. This ICR concerns two such additions. This ICR includes both the former ''Reporting and Recordkeeping Requirements for Universal Waste Handlers and Destination Facilities'' ICR (EPA ICR Number 1597.04, OMB Control Number 2050–0145) and the ''Storage, Treatment, and Disposal of Mixed Waste'' ICR (EPA ICR Number 1922.02, OMB Control Number 2050–0181).

In 1995, EPA promulgated regulations in 40 CFR part 273 that govern the collection and management of widely-generated hazardous wastes known as ''Universal Wastes''. Universal Wastes are wastes that are generated in non-industrial settings by a vast community, and are present in non-hazardous waste management systems. Examples of Universal Wastes include certain batteries, pesticides, mercury-containing lamps and thermostats. The part 273 regulations are designed to separate Universal Waste from the municipal wastestream by encouraging individuals and organizations to collect these wastes and to manage them in an appropriate hazardous waste management system. EPA distinguishes two types of handlers of Universal Wastes: Small quantity handlers of Universal Waste (SQHUW) and large quantity handlers of Universal Waste (LQHUW). SQHUWs do not accumulate more than 5,000 kg of any one category of Universal Waste at one time, while LQHUWs may accumulate quantities at or above this threshold. More stringent requirements are imposed on LQHUWs because of greater potential environmental risks.

In 2001, EPA promulgated regulations in 40 CFR part 266 that provide increased flexibility to facilities managing wastes commonly known as ''Mixed Waste''. Mixed Waste are low-level mixed waste (LLMW), and naturally occurring and/or accelerator-produced radioactive material (NARM) containing hazardous waste. These wastes are also regulated by the Atomic Energy Act. As long as specified eligibility criteria and conditions are met, LLMW and NARM are exempt from the definition of hazardous waste as defined in part 261. Although these eligible wastes are exempted from RCRA manifest, transportation, and disposal requirements, they must still comply with the manifest, transportation, and disposal requirements under the NRC (or NRC-Agreement State) regulations. There are two conditional exemptions. The Storage and Treatment Conditional Exemption applies to any generator of LLMW who is licensed by NRC or an NRC Agreement State to manage radioactive materials. This exemption is available only to LLMW generated under a single NRC or NRC Agreement State license. LLMW generators must notify EPA of the LLMW storage units for which they are claiming an exemption, and must meet the conditions listed in section 266.230. This exemption is valid as long as the Mixed Waste meets the conditions, remains in a conditionally exempt storage unit, and is subject to NRC regulation.

The Transportation and Disposal Conditional Exemption from the definition of hazardous waste applies to generators and treaters who send their treated waste to a commercial low-level radioactive waste disposal facility (LLRWDF) licensed by NRC or NRC Agreement State. The eligible LLMW or

NARM waste would be exempted from RCRA Subtitle C once it is placed on the transportation vehicle bound for disposal at the LLRWDF. The waste could then be transported to the LLRWDF as strictly radioactive waste using an NRC Uniform LLW Manifest. Generators and treaters under the exemption must undertake the information collection requirements listed in section 266.345.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Business, farms, State, Local, or Tribal Governments.

Estimated Number of Respondents: 119,782.

Frequency of Response: On occasion.

Estimated Total Annual Hour Burden: 185,967.

Estimated Total Annual Cost: $10,730,000, includes $2,000 annual startup/capital costs, $1,000 annual O&M costs and $10,727,000 annual labor costs.

Changes in the Estimates: There is a decrease of 32,201 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is due to a decrease in the number of both large quantity Universal Waste handlers, as well as generators of Mixed Waste, since the last time this ICR was approved.

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26074 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OW–2004–0007; FRL–7841–3]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Public Water System Supervision Program (Renewal), EPA ICR Number 0270.42, OMB Control Number 2040–0090

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on November 30, 2004.Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OW–2004–0007, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Water Docket, Mail Code 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Richard P. Naylor, Office of Ground Water and Drinking Water, Mail Code 4606M, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202.564.3847; fax number: 202.564.3755; e-mail address: *naylor.richard@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On April 30, 2004 (69 FR 23743), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OW–2004–0007, which is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Public Water System Supervision Program (Renewal).

Abstract: The Public Water System Supervision Program ICR examines public water system (PWS), primacy agency and EPA burden and costs for

''cross-cutting'' recordkeeping and reporting requirements (*i.e.*, the burden and costs for complying with drinking water information requirements that are not associated with contaminant-specific rulemakings). These activities which have recordkeeping and reporting requirements that are mandatory for compliance with 40 CFR parts 141 and 142 include the following: Consumer Confidence Reports, Primacy Regulation Activities, Variance and Exemption Rule, General State Primacy Activities, Constructed Conveyances, and Public Notification. The information collection activities for both the Operator Certification/Expense Reimbursement Program and the Capacity Development Program are driven by the grant withholding and reporting provisions under sections 1419 and 1420, respectively, of the Safe Drinking Water Act. Although the Tribal Operator Certification Program is voluntary, the information collection is driven by grant eligibility requirements outlined in the Drinking Water Infrastructure Grant Tribal Set-Aside Program Final Guidelines and the Tribal Drinking Water Operator Certification Program Guidelines.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 6.5 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: (1) Owners/operators of PWSs, who must report to the primacy agency; (2) primacy agencies that must report to EPA Headquarters; and (3) regional EPA administrators, who must send reports and notices to PWS owners and states.

Estimated Number of Respondents: 161,682.

Frequency of Response: 24 hours, quarterly, annually, every 3 years.

Estimated Total Annual Hour Burden: 3,223,430.

Estimated Total Annual Cost: $116,457,000, includes $19,716,000 annualized capital or O&M costs and $96,741,000 annual labor costs.

Changes in the Estimates: There is an increase of 601,582 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is primarily due to (1) restructuring adjustments—incorporation of previously stand-alone ICRs (Operator Certification Program/Expense Reimbursement Grants and Tribal Operator Certification Program), (2) inclusion of three full years of the Public Notification Rule burden along with an increase in Tier 3 violations and (3) a change in requirements associated with the new PWS definition.

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26075 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OW–2004–0008; FRL–7841–4]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Microbial Rules (Renewal), EPA ICR Number 1895.03, OMB Control Number 2040–0205

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on November 30, 2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OW–2004–0008, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *OW–Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Water Docket, Mail Code 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Richard P. Naylor, Office of Ground Water and Drinking Water, (4606M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202.564.3847; fax number: 202.564.3755; e-mail address: *naylor.richard@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On April 30, 2004 (69 FR 23741), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OW–2004–0008, which is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When

EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Microbial Rules (Renewal).

Abstract: This ICR examines public water system (PWS), primacy agency, and EPA burden and costs for recordkeeping and reporting required in support of microbial contaminant-associated rulemakings. These rules that have recordkeeping and reporting requirements that are mandatory for compliance with 40 CFR parts 141 and 142 include the following: (1) Surface Water Treatment Rule (SWTR); (2) Total Coliform Rule (TCR); (3) Interim Enhanced Surface Water Treatment Rule (IESWTR); (4) Filter Backwash Recycling Rule (FBRR); and (5) Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR). This Microbial Rules ICR includes all SWTR components except disinfectant residual monitoring and associated activities, which are included in the Disinfectants and Disinfection Byproducts, Chemical, and Radionuclides Rules ICR. Burden for future rules that address microbial contaminants (Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), and the Ground Water Rule (GWR) will be added to this ICR when the regulations are finalized and the original stand-alone ICRs for each rule expires.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average .77 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: (1) Owners/operators of PWSs, who must report to the primacy agency; (2) primacy agencies that must report to EPA Headquarters; and (3) regional EPA administrators, who must send reports and notices to PWS owners and States.

Estimated Number of Respondents: 161,274.

Frequency of Response: As necessary, monthly, quarterly, annually.

Estimated Total Annual Hour Burden: 8,624,865.

Estimated Total Annual Cost: $340,480,000, includes $96,939,000 annualized capital or O&M costs and $243,541,000 annual labor costs.

Changes in the Estimates: There is an increase of 431,665 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is primarily due to restructuring adjustments (*i.e.*, incorporation of previously stand-alone ICRs for the LT1ESWTR and the FBRR).

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26076 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OW–2004–0015; FRL–7841–5]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Clean Water Act State Revolving Fund Program (Renewal), EPA ICR Number 1391.07, OMB Control Number 2040–0118

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on 11/30/2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OW–2004–0015, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *OW-Docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Water Docket, Mail Code 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Clifford Yee, Office of Wastewater Management, Mail Code 4204M, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–564–0598; fax number: 202–501–2403; e-mail address: *yee.clifford@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 5, 2004 (69 FR 47432), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OW–2004–0015, which is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically.

Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Clean Water Act State Revolving Fund Program (Renewal).

Abstract: The Clean Water Act, as amended by ''The Water Quality Act of 1987'' (U.S.C. 1381–1387 *et. seq.*), created a Title VI which authorizes grants to States for the establishment of State Water Pollution Control Revolving Funds (SRFs). The information collection activities will occur primarily at the program level through the State ''Intended Use Plan'' and ''Annual Report.'' The information is needed annually to implement section 606 of the Clean Water Act (CWA).

The 1987 Act declares that water pollution control revolving funds shall be administered by an instrumentality of the State subject to the requirements of the act. This means that each State has a general responsibility for administering its revolving fund and must take on certain specific responsibilities in carrying out its administrative duties. The information collection activities will occur primarily at the program level through the State Intended Use Plan and Annual Report. The information is needed annually to implement section 606 of the Clean Water Act (CWA). The Act requires the information to ensure national accountability, adequate public comment and review, fiscal integrity and consistent management directed to achieve environmental benefits and results. The individual information collections are: (1) Capitalization Grant Application and Agreement/State Intended Use Plan, (2) Annual Report, (3) State Annual Audit, and (4) Application for SRF Financial Assistance.

(1) *Capitalization Grant Application and Agreement/State Intended Use Plan:* The State will prepare a Capitalization Grant application that includes an Intended Use Plan (IUP) outlining in detail how it will use all the funds available to the fund. The grant agreement contains or incorporates by reference the IUP, application materials, payment schedule, and required assurances. The bulk of the information is provided in the IUP, the legal agreement which commits the State and EPA to execute their responsibilities under the Act.

(2) *Annual Report:* The State must agree to complete and submit an Annual Report that indicates how the State has met the goals and objectives of the previous fiscal year as stated in the IUP and grant agreement. The report provides information on loan recipients, loan amounts, loan terms, project categories, and similar data on other forms of assistance. The report describes the extent to which the existing SRF financial operating policies, alone or in combination with other State financial assistance programs, will provide for the long term fiscal health of the Fund and carry out other provisions specified in the grant operating agreement.

(3) *Annual Audit:* Most States have agreed to conduct or have conducted a separate financial audit of the Capitalization Grant which will provide opinions on the financial statements, and a report on the internal controls and compliance with program requirements. The remaining States will be covered by audits conducted under the requirements of the Single Audit Act and by EPA's Office of Inspector General.

(4) *Application for SRF Financial Assistance:* Local communities and other eligible entities have to prepare and submit applications for SRF assistance to their respective State Agency which manages the SRF program. The State reviews the completed loan applications, and verifies that the proposed projects will comply with applicable Federal and State requirements.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 111 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: 3,009.

Estimated Number of Respondents: 3,060.

Frequency of Response: Annually.

Estimated Total Annual Hour Burden: 339,405.

Estimated Total Annual Cost: $6,155,700, includes $0 annual capital/startup and O&M costs and $6,155,700 annual labor costs.

Changes in the Estimates: There is an increase of 76,500 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is due to the increase in the number of participants in the program, the individual burden still remains the same.

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26077 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2004–0228; FRL–7841–6]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Reporting and Recordkeeping Requirements Under the Perfluorocompound (PFC) Reduction/Climate Partnership for the Semiconductor Industry (Renewal), EPA ICR Number 1823.03, OMB Control Number 2060–0382

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on 11/30/04. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OAR–2004–0228, to (1) EPA online using EDOCKET (our preferred method), by E-mail to *a-and-r-Docket@epa.gov*, or by mail to: Environmental Protection Agency, EPA Docket Center (EPA/DC), Air and Radiation Docket and Information Center, MC 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Scott Bartos, Office of Atmospheric Programs, 6207J, Environmental Protection Agency, 1200 Pennsylvania Aveue, NW., Washington, DC 20460; telephone number: (202) 343–9167; fax number: (202) 343–2202; e-mail address: *bartos.scott@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On August 23, 2004 (69 FR 51831), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OAR–2004–0228, which is available for public viewing at the Air and Radiation Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Reporting and Record Keeping Requirements Under the Perfluorocompound (PFC) Reduction/Climate Partnership for the Semiconductor Industry (Renewal).

Abstract: The U.S. EPA's Office of Atmospheric Programs launched the PFC Reduction/Climate Partnership for the Semiconductor Industry in 1996. Perfluorinated compounds (PFCs) are the most potent greenhouse gases known with atmospheric lifetimes of up to 50,000 years. These unique chemical compounds are required during two critical semiconductor manufacturing steps, plasma etching and CVD chamber cleaning. This important voluntary program contributes to the country's overall reduction in greenhouse gas emissions. The program uses a pollution prevention approach to reduce emissions and tracks progress by annually collecting PFC emissions estimates from partners.

In 2003, EPA's semiconductor industry partners were recognized for their commitment and ongoing efforts to protect the climate as participants in the White House's Climate VISION initiative. All semiconductor manufacturers operating in the U.S. are invited to join this voluntary partnership. Participation in the program begins by completing a Memorandum of Understanding that defines a voluntary agreement between the company and EPA. By joining the partnership, a company agrees to track and report an estimate of its PFC emissions to EPA annually. A designated third party assembles the reported data and protects any confidential or sensitive information prior to EPA review. The partner companies' annual reports will provide an estimate of total PFC emissions and a description of the estimating method. The partnership will track progress as a group using the aggregate annual PFC emissions estimate.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 533 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Semiconductor manufacturers.

Estimated Number of Respondents: 24.

Frequency of Response: Once annually.

Estimated Total Annual Hour Burden: 13,050.

Estimated Total Annual Cost: $1,253,982, which includes $0 annualized capital/startup costs,

$132,936 annual O&M costs, and $1,121,046 annual labor costs.

Changes in the Estimates: There is a decrease of 1,900 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is because the partnership has stabilized at 24 partner companies representing 80 percent of the U.S. industry and no new partners are expected to join over the next three years. Therefore, activities related to reviewing and signing a memorandum of understanding were removed from the burden estimate.

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26078 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2004–0082, FRL–7841–7]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Reporting and Recordkeeping Requirements Under EPA's Natural Gas STAR Program (Renewal), ICR Number 1736.04, OMB Number 2060–0328

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on November 30, 2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before December 27, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OAR–2004–0082, to EPA online using EDOCKET (our preferred method), by E-mail to *a-and-r-Docket@epa.gov,* or by mail to: Environmental Protection Agency, EPA Docket Center (EPA/DC), Air and Radiation Docket and Information Center, MC 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Kevin Tingley, Natural Gas STAR Program, U.S. Environmental Protection Agency, Mail Code 6207J, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 343–9086; fax number: (202) 343–2208; e-mail address: *tingley.kevin@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On June 29, 2004 (69 FR 38893), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OAR–2004–0082, which is available for public viewing at the Air and Radiation Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Title: Reporting and Recordkeeping Requirements Under EPA's Natural Gas STAR Program (Renewal).

Abstract: Natural Gas STAR is an EPA-sponsored, voluntary program that encourages natural gas companies to adopt cost effective methods for reducing methane emissions. Natural Gas STAR Partners agree to implement cost-effective Best Management Practices, which will save participants money and improve environmental quality. EPA needs to collect information to establish program participation and to obtain general information on new Natural Gas STAR Partners. EPA also uses the information collection to evaluate a Partner's progress and performance, assess overall program results, and develop technical guidance documents for the benefit of the industry. Information collection is accomplished through the use of an annual reporting process that allows companies to report their accomplishments in either a traditional hard-copy format or electronically. Participation in Natural Gas STAR is voluntary. Natural Gas STAR Partners may designate information submitted under this ICR as confidential business information. EPA will treat all such information as confidential business information and will not make the company or agency-specific information collected under this ICR available to the general public.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

OMB has requested that EPA determine the extent to which reductions reported to the Natural Gas STAR Program would have occurred in the absence of the program. EPA has performed a sensitivity analysis in order to address this issue. Details are provided in the Supporting Statement for this notice.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 44 hours per response. Burden means the total time, effort, or financial resources expended

by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Natural Gas Companies.

Estimated Number of Respondents: 108.

Frequency of Response: Varies.

Estimated Total Annual Hour Burden: 4,705.

Estimated Total Annual Cost: $402,162, which includes $0 annualized capital/startup costs, $21 annual O&M costs, and $402,141 annual labor costs.

Changes in the Estimates: There is an increase of 646 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is due to an increased number of program participants, but is tempered by a reduction in the amount of time spent filling out and submitting the annual report due to the introduction of on-line reporting in 2002.

Dated: November 17, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–26079 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Petition IV–2003–1; FRL–7842–2]

Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permit for Hercules, Inc.; Brunswick (Glynn County), GA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition to object to a state operating permit.

SUMMARY: Pursuant to section 505(b)(2) of the Clean Air Act (the Act) and 40 CFR 70.8(d), the EPA Administrator signed an order, dated November 10, 2004, denying a petition to object to a state operating permit issued by the Georgia Environmental Protection Division (EPD) to Hercules, Inc. (Hercules) located in Brunswick, Glynn County, Georgia. This order constitutes final action on the petition submitted by the Glynn Environmental Coalition and the Center for a Sustainable Coast (Petitioners). Pursuant to section 505(b)(2) of the Act, any person may seek judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of this notice under section 307 of the Act.

ADDRESSES: Copies of the final order, the petition, and all pertinent information relating thereto are on file at the following location: EPA Region 4, Air, Pesticides and Toxics Management Division, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The final order is also available electronically at the following address: *http://www.epa.gov/region7/programs/artd/air/title5/petitiondb/petitions/hercules_decision2003.pdf.*

FOR FURTHER INFORMATION CONTACT: Art Hofmeister, Air Permits Section, EPA Region 4, at (404) 562–9115 or *hofmeister.art@epa.gov*.

SUPPLEMENTARY INFORMATION: The Act affords EPA a 45-day period to review and, as appropriate, to object to operating permits proposed by state permitting authorities under title V of the Act, 42 U.S.C. 7661–7661f. Section 505(b)(2) of the Act and 40 CFR 70.8(d) authorize any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of EPA's 45-day review period if EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

On January 23, 2003, the Administrator received a petition requesting that EPA object to a state title V operating permit issued by EPD to Hercules. The Petitioners maintain that the Hercules permit is inconsistent with the Act because: (1) The permit fails to include all applicable requirements, specifically Georgia Rule 391–3–1–.02(2)(a)1. and (2) the permit fails to assure compliance with said rule.

On November 10, 2004, the Administrator issued an order denying this petition. The order explains the reasons behind EPA's conclusion that the Petitioners failed to demonstrate that the Hercules permit is not in compliance with the requirements of the Act on the grounds raised.

Dated: November 18, 2004.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

[FR Doc. 04–26080 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7841–9]

Clean Air Scientific Advisory Committee Science Advisory Board (SAB) Staff Office Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel; Additional Opportunity To Submit Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office is reopening the public nomination process for experts to serve on the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (Panel), and is hereby soliciting additional nominations for this Panel.

DATES: New nominations should be submitted by December 8, 2004.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Request for Nominations may contact Mr. Fred Butterfield, Designated Federal Officer (DFO), EPA Science Advisory Board Staff, at telephone/voice mail: (202) 343–9994; or via e-mail at: *butterfield.fred@epa.gov*. General information concerning the CASAC or the SAB can be found on the EPA Web site at: *http://www.epa.gov/sab*.

SUPPLEMENTARY INFORMATION:

Background: The CASAC, which comprises seven members appointed by the EPA Administrator, was established under section 109(d)(2) of the Clean Air Act (42 U.S.C. 7409) as an independent scientific advisory committee, in part to provide advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and NAAQS under sections 108 and 109 of the Act. The CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App.

The SAB Staff Office previously announced in the **Federal Register** in June 2003 (68 FR 35212, June 12, 2003) the formation of the CASAC Ozone Review Panel, to conduct reviews of

EPA's updated ambient air quality criteria and the science-based national ambient air quality standards (NAAQS) for ozone and other photochemical oxidants. The Ozone Review Panel will consist of the seven members of the statutory (chartered) CASAC and additional experts as necessary to provide advice and recommendations related to the science of ozone and other photochemical oxidants. The Ozone Review Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

In response to the June 12, 2003 notice in the **Federal Register**, the SAB Staff Office has received nominations for additional scientific experts and has previously published a ''Short List'' of candidates on the SAB Web site (*http://www.epa.gov/sab*) for the purpose of soliciting public comments. Given the lengthy period of time that has elapsed since its first announcement, the SAB Staff Office is reopening the public nomination process for experts to serve on this Panel. Nominator's Assessment of Expertise. When submitting nominations to the CASAC Ozone Review Panel, please explicitly indicate the specific areas of expertise the candidate could contribute. The CASAC requests nominees who are recognized, national-level experts in one or more of the following disciplines:

(a) *Atmospheric Science.* Expertise in physical/chemical properties of ozone and other photochemical oxidants, their precursor substances, and atmospheric processes involved in the formation, transport, and degradation of ozone and other photochemical oxidants in the atmosphere, including interaction with global climate and stratospheric ozone. Also, expertise in the evaluation of natural and man-made (anthropogenic) sources and emissions of precursors of tropospheric ozone and other photochemical oxidants, pertinent monitoring/measurement methods for such substances, and spatial/temporal trends in atmospheric concentrations of them.

(b) *Exposure and Risk Assessment/Modeling.* Expertise in measuring human population exposure to ozone and/or in modeling human exposure to ambient and indoor pollutants. Also, expertise in human health risk analysis modeling for ozone or other pollutants causing respiratory and/or other non-cancer health effects.

(c) *Ecological Effects and Resource Valuation.* Expertise in evaluation of: patterns of exposure to ozone and/or other photochemical oxidants of ornamental and/or agricultural plants and/or natural ecosystems and their components; effects of ozone and other photochemical oxidants on natural ecosystems (especially terrestrial) and their components (both flora and fauna), ranging from biochemical/sub-cellular effects and identification of indicators of pathophysiological effects at the individual plant level, to effects on species and populations, on up to include impacts on increasingly more complex (*e.g.*, landscape) levels of ecosystem organization. Also, expertise in (i) ecosystem risk assessment and (ii) ecological resource valuation/economics.

(d) *Dosimetry.* Expertise in conducting and/or evaluation of the dosimetry of animal and human subjects, and animal-to-human dosimetry extrapolations, including identification of factors determining differential patterns of inhalation and/or deposition/uptake in respiratory tract regions that may contribute to differential susceptibility of human population subgroups to ozone and other photochemical oxidants.

(e) *Toxicology.* Expertise in conducting and/or evaluation of experimental laboratory animal studies of the potential health effects of ozone and/or other photochemical oxidants on respiratory and non-respiratory (*e.g.*, lung defense/other immune function mechanisms) endpoints.

(f) *Controlled Human Exposure.* Expertise in conducting and/or evaluation of controlled human exposure studies of the effects of ozone and other photochemical oxidants on healthy and compromised (having pertinent preexisting chronic disease, *e.g.*, asthma) human adults and children, including medical doctors (M.D.) with experience in the clinical treatment of asthma.

(g) *Epidemiology and Biostatistics.* Expertise in epidemiological evaluation of the effects of exposures to ozone and other photochemical oxidants and/or other ambient air co-pollutants on human population groups, including effects on mortality and/or morbidity (*e.g.*, respiratory symptoms, lung function decrements, asthma medication use, respiratory-related hospital admissions) endpoints. Also, expertise in associated biostatistics and/or health risk analysis.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals to add expertise to the CASAC Ozone Review Panel in the areas of expertise described above. Nominations should be submitted in electronic format through the Form for Nominating Individuals to Panels of the EPA Science Advisory Board provided on the SAB Web site, *http://www.epa.gov/sab*, which can be accessed through a link on the blue navigational bar on the SAB Web page. To be considered, all nominations must include the information required on that form. Please note that there is no need to resubmit a nomination for an individual who has previously been nominated for the CASAC Ozone Review Panel.

Anyone who is unable to submit nominations using this form, and any questions concerning any aspects of the nomination process may contact Mr. Fred Butterfield, DFO, as indicated above in this notice. Nominations should be submitted in time to arrive no later than December 8, 2004.

To be considered, all nominations must include: (a) a current biography, curriculum vitae (C.V.) or resume, which provides the nominee's background, experience and qualifications for the Panel; and (b) a brief biographical sketch (''biosketch''). The biosketch should be no longer than one page and must contain the following information for the nominee:

(I) Current professional affiliations and positions held;

(ii) Area(s) of expertise, and research activities and interests;

(iii) Leadership positions in national associations or professional publications or other significant distinctions;

(iv) Educational background, especially advanced degrees, including when and from which institutions these were granted;

(v) Service on other advisory committees, professional societies, especially those associated with issues under discussion in this review; and

(vi) Sources of recent (*i.e.*, within the preceding two years) grant and/or other contract support, from government, industry, academia, etc., including the topic area of the funded activity.

Please note that even if there is no responsive information (*e.g.*, no recent grant or contract funding), this must be indicated on the biosketch (by ''N/A'' or ''None''). Incomplete biosketches will result in nomination packages not being accepted.

The EPA SAB Staff Office will acknowledge receipt of the nomination. From the nominees identified by respondents to this notice (termed the ''Widecast''), the SAB Staff Office will develop a smaller subset (known as the ''Short List'') for more detailed consideration. Criteria used by the SAB Staff in developing this Short List are given at the end of the following paragraph. The Short List will be posted on the SAB Web site at: *http://www.epa.gov/sab*, and will include, for each candidate, the nominee's name and

their biosketch. Public comments will be accepted for 21 calendar days on the Short List. During this comment period, the public will be requested to provide information, analysis or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates for the Panel.

For the EPA SAB Staff Office, a balanced subcommittee or review panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. Public responses to the Short List candidates will be considered in the selection of the Panel, along with information provided by candidates and information independently-gathered by the SAB Staff Office on the background of each candidate (*e.g.*, financial disclosure information and computer searches to evaluate a nominee's prior involvement with the topic under review). Specific criteria to be used in evaluating an individual member of the Panel include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) scientific credibility and impartiality; and (e) skills working in advisory committees, subcommittees and review panels. CASAC Ozone Review Panel members will likely be asked to attend two to three public, face-to-face meetings and several public teleconference meetings per year over the anticipated two- to-five-year course of the Panel's activity.

Short List candidates will also be required to fill-out the ''Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency'' (EPA Form 3110–48). This confidential form allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities (which includes membership on an EPA Federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded from the following URL address: *http://www.epa.gov/sab/pdf/epaform3110–48.pdf*.

The approved policy under which the EPA SAB Office selects subcommittees and review panels is described in the following document: Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board (EPA–SAB–EC–02–010), which is on the SAB Web site at: *http://www.epa.gov/sab/pdf/ec02010.pdf*.

Dated: November 18, 2004.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 04–26081 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0078; FRL–7688–5]

Certain Ethylenebisdithiocarbamates (EBDCs) and Ethylene Thiourea (ETU); Risk Assessments and Preliminary Risk Reduction Options (Phase 3 of 4-Phase Process); Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's risk assessments, preliminary risk reduction options, and related documents for the ethylenbisdithiocarbamates (EBDCs) pesticides mancozeb, maneb, metiram, plus a common degradate, ethylene thiourea (ETU), and opens a public comment period on these documents. The public also is encouraged to suggest risk management ideas or proposals to address the risks identified. EPA is developing a Reregistration Eligibility Decision (RED) for mancozeb, maneb, metiram, which will include a common degradate, ETU through a modified, 4-Phase public participation process that the Agency uses to involve the public in developing pesticide reregistration and tolerance reassessment decisions. Through these programs, EPA is ensuring that all pesticides meet current health and safety standards.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0078, must be received on or before February 22, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Anthony Britten (Mancozeb), telephone number: (703) 308–8179; fax number: (703) 308–8005; e-mail address: britten.anthony@epa.gov and Tawanda Spears (Maneb & Metiram), telephone number: (703) 308–8050; fax number: (703) 308–8005; e-mail address: *spears.tawanda@epa.gov*. Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0078. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,''

then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0078. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp–docket@epa.gov*, Attention: Docket ID Number OPP–2004–0078. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0078.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0078. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Background

A. What Action is the Agency Taking?

EPA is releasing for public comment its human health and environmental fate and effects risk assessments, preliminary risk reduction options, and related documents for the EBDCs: Mancozeb, maneb, metiram, plus a common degradate, ETU and encouraging the public to suggest risk management ideas or proposals. EPA developed the risk assessments and preliminary risk reduction options for the EBDCs: Mancozeb, maneb, metiram, plus a common degradate, ETU through a modified version of its public process for making pesticide reregistration eligibility and tolerance reassessment decisions. Through these programs, EPA is ensuring that pesticides meet current standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

The EBDCs are used on a variety of sites such as: Agricultural crops (vegetables, fruits and nuts); turf (including golf courses and sod farms); and ornamentals (such as cut flowers). The EBDCs are broad spectrum contact fungicides used to prevent a variety of fungal diseases. Each of these chemicals also share a common degradate, ETU. The majority of the risk concerns are associated with the degradate ETU, which EPA has classified as a probable human carcinogen. EPA aggregated (added) to ETU several routes of exposure (food, drinking water, and residential/recreational) to determine if there are combined risks of concern for individual uses that currently fit in the ''risk cup.''

All elements of the Agency's risk assessments for the EBDCs are open for public comment. We are, however, particularly seeking public comment on data refinement or mitigation proposals for risk estimates of concern identified in the Agency's risk assessments and in a stand-alone document titled ''Preliminary Risk Reduction Options for the EBDCs (Phase 3 of 4-Phase Process),'' available in the docket. The document addresses, for example, data that may help refine risk estimates for residential exposure to turf transplanted from sod farms, depending on how close to harvest sod farms apply EBDCs to turf, and how the harvested turf is installed by landscape professionals. Similarly, information on how EBDCs are used on athletic fields may refine estimated risks of concern. Mitigation proposals for both these use patterns will be helpful if new information does not refine risk estimates.

EPA also welcomes data to refine risk estimates for certain use patterns that impact aggregate risks, even though the individual use pattern is not of concern. Examples of useful information include: how homeowners use EBDCs in gardens (particularly relative to harvesting sweet corn); use practices for EBDCs on golf courses; and percent crop treated refinements for certain key crops. For some scenarios, such as occupational uses of wettable powders, new data are unlikely to significantly refine risks and mitigation proposals are needed. For occupational uses where cancer risks fall between 1×10^{-4} and 1×10^{-6}, EPA will need to consider any comments submitted on risks and benefits of the use. Information on the prevalence of late blight for potatoes, and EBDC use to control it, would help EPA evaluate issues relevant to a petition for nationwide reduction of the pre-harvest interval (PHI). For ecological risks, EPA would welcome specific information such as: Timing and location of EBDC applications relative to avian and mammalian reproduction cycles and habitats; potential impacts to endangered species in light of EPA's screening level assessment; and data refinement or mitigation proposals for effects on aquatic species.

EPA is providing an opportunity, through this notice, for interested parties to provide comments and input on the Agency's risk assessments for mancozeb, maneb, metiram, plus a common degradate, ETU. Such comments and input could address, for example, the availability of additional data to further refine the risk assessments, or could address the Agency's risk assessment methodologies and assumptions as applied to this specific pesticide.

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have a typical, unusually high exposure to mancozeb, maneb, metiram, plus a common degradate, ETU, compared to the general population.

EPA also is releasing for public comment its preliminary risk reduction options for mancozeb, maneb, metiram, plus a common degradate, ETU, and is providing an opportunity for interested parties to provide risk management proposals or otherwise comment on risk management.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** on May 14, 2004 (69 FR 26819) (FRL–7357–9), explains that in conducting these programs, the Agency is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of the issues, and degree of public concern associated with each pesticide. For mancozeb, maneb, metiram, plus a common degradate, ETU, a modified, 4-Phase process with 1 comment period and ample opportunity for public consultation seems appropriate in view of its limited risk concerns. However, if as a result of comments received during this comment period EPA finds that additional issues warranting further discussion are raised, the Agency may lengthen the process and include a second comment period, as needed.

All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. Comments will become part of the Agency Docket for mancozeb, maneb, metiram, plus a common degradate, ETU. Comments received after the close of the comment period will be marked ''late.'' EPA is not

required to consider these late comments.

B. What is the Agency's Authority for Taking this Action?

Section 4(g)(2) of FIFRA as amended directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product specific data on individual end-use products and either reregistering products or taking other ''appropriate regulatory action.''

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: November 16, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–26132 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0239; FRL–7675–5]

MCPA; Availability of Reregistration Eligibility Decision Document for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces availability and starts a 60–day public comment period on the Reregistration Eligibility Decision (RED) document for the pesticide active ingredient 4-chloro-2-methylphenoxyacetic acid (MCPA). The RED represents EPA's formal regulatory assessment of the health and environmental data base of the subject chemical and presents the Agency's determination regarding which pesticidal uses are eligible for reregistration.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0239, must be received on or before January 24, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kelly White, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–8401; e-mail address: *white.kelly@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or the Federal Food, Drug, and Cosmetic Act (FFDCA); environmental, human health, and agricultural advocates; pesticides users; and members of the public interested in the use of pesticides. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0239. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. To access RED documents and RED fact sheets electronically, go directly to the RED table on the EPA Office of Pesticide Programs Home Page, at *http://www.epa.gov/pesticides/reregistration/status.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or

delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0239. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2004–0239. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2004–0239.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2004–0239. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

The Agency has issued a RED for the pesticide active ingredient listed in this document. Under the FIFRA, as amended in 1988, EPA is conducting an accelerated reregistration program to reevaluate existing pesticides to make sure they meet current scientific and regulatory standards. The data base to support the reregistration of the chemical listed in this document is substantially complete, and the pesticide's risks has been mitigated so that it will not pose unreasonable risks to people or the environment when used according to its approved labeling. In addition, EPA is reevaluating existing pesticides and reassessing tolerances under the Food Quality Protection Act (FQPA) of 1996. The pesticide included in this notice also has been found to meet the FQPA safety standard.

All registrants of the pesticide product containing the active ingredient listed in this document have been sent the appropriate RED, and must respond to labeling requirements and product-specific data requirements (if applicable) within 8 months of receipt. Products also containing other pesticide active ingredients will not be reregistered until those other active ingredients are determined to be eligible for reregistration.

The reregistration program is being conducted under Congressionally mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing the RED as a final document with a 60–day comment period. Although the 60–day public comment period does not affect the registrant's response due date, it is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the RED. If any comment significantly affects a RED, EPA will amend the RED by publishing the amendment in the **Federal Register**.

B. What is the Agency's Authority for Taking this Action?

The legal authority for the RED falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product-specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: November 2, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–25944 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0296; FRL–7685–3]

Captan; Cancer Reclassification; Amendment of ReregistrationEligibility Decision; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's modification of certain provisions of the 1999 Reregistration Eligibility Decision (RED) for the pesticide captan, and opens a public comment period on these changes. EPA is amending the captan RED in response to public comments received. EPA has made certain modifications to the captan RED which are discussed in the ''Amendment to the 1999 Captan RED'' document, which is available in the captan docket and e-docket. This notice also opens the public comment period announcing the results of the Agency's reevaluation of captan's cancer classification. The Captan Task Force voluntarily pursued a process to reclassify captan's initial cancer classification, as a probable human carcinogen, by supporting a third-party review of data to support a mode of action determination for captan. Based on the third-party review and subsequent Agency review, EPA has determined that captan acts through a non-genotoxic threshold mode of action. Although the Agency is issuing a single FR to announce both the amendment to the RED and the reevaluation of the cancer classification, the change in cancer classification does not change the risk management conclusions nor amend the 1999 Captan RED, and is not considered a reregistration action.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0296, must be received on or before January 24, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: *For questions regarding the cancer reclassification*: Susan Jennings, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (706) 355–8574; e-mail address: *jennings.susan@epa.gov*.

For questions regarding the ''Amendment to the 1999 Captan RED'' document: Cathryn O'Connell, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0136; e-mail address:*oconnell.cathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0296. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket,

will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0296. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0296. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0296.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0296. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

The Agency is issuing an ''Amendment to the 1999 Captan RED'' document for public comment. In addition, this notice announces the results of the Agency's reevaluation of captan's cancer classification. This reevaluation does not change the conclusions of the RED and does not amend the Captan RED.

i. *Amendment to the 1999 Captan RED*. In 1999, EPA issued a RED for captan under section 4(g)(2)(A) of FIFRA. EPA has modified certain captan label requirements including: Double notification for all agricultural uses of captan; verbal notification of eye concerns associated with captan for 7 days following application; wettable powders applied aerially to be formulated in water soluble packages; reductions in the dichondra ornamental grass use rate; establishing a Re-Entry Interval for ornamentals, blackberries, blueberries, dewberries, raspberries, and grapes of 48 hours; removing the dust/mist respirator requirement for handling bags of treated seed.

ii. *Cancer reclassification*. When the RED was issued, captan retained its previous classification as a B2 chemical carcinogen (probable human carcinogen). Cancer risk from captan was quantified using the Agency's default approach described in the Agency's 1986 Cancer Risk Assessment Guidelines. When much uncertainty exists regarding the mode of carcinogenic action, EPA assumes the tumor dose response from a cancer study is linear. In the absence of adequate information to the contrary, the linearized multistage procedure is applied to the tumor response data to calculate the cancer unit risk (Q1*), which is the upper confidence limit (95th percentile) of the dose response curve. This linear low dose approach used to estimate cancer risk is believed to be conservative.

Although the Captan Task Force (CTF) had submitted several mechanism studies for captan, the Agency determined that they did not contribute sufficient additional information to the mode of action nor have a significant bearing on the cancer risk assessment. In the RED, the Agency reaffirmed its decision that the linear low dose extrapolation model should continue to be used for risk assessment and determined that a reconsideration for captan according to the 1996 Draft Cancer Risk Assessment guidelines was not required.

In February of 2000, the CTF petitioned the Agency to reevaluate the cancer risk assessment for captan using a threshold approach rather than the traditional linear low dose (Q1*) approach. They submitted additional data, including data on thiophosgene, and stated that they strongly believed that captan should be regulated as a threshold carcinogen. Their comments were bolstered by portions of the RED, which stated that ''the carcinogenic process is thought to be triggered by the highly reactive but short-lived metabolite thiophosgene.''

When the Agency reviewed this petition and additional data, it concluded that the information might be sufficient to warrant a cancer reclassification. However, the Agency also concluded that the resources required to conduct a thorough reclassification effort would not be available in the short-term. Since the reclassification would not change the conclusions of the RED, namely that the risk of cancer from exposure to captan was below the Agency's level of concern, the Agency determined that reevaluating captan's cancer classification was not a priority action at that time and was not necessary to reregister end-use products containing captan.

In 2001, based on a request from the CTF, EPA agreed to consider a re-evaluation of captan's cancer classification by a third party. It was envisioned that an organization, separate from the CTF, would manage an expert scientific peer review of the cancer information, and generate the supporting documentation and proposed conclusion from the third party. The Agency would then review the work of the third party and make its own decision regarding captan's cancer reclassification. The Agency was available for consultation, but did not manage or approve any portion of these proceedings. Records of interactions between the Agency and the CTF regarding this process are available in the public docket.

The CTF chose Toxicology Excellence for Risk Assessment (TERA) to recruit and manage the process of reviewing the captan cancer mode of action data. On September 3 and 4, 2003, a third party of outside experts in various fields and affiliations reviewed the captan cancer mode of action data. This Peer Review Panel concluded that captan acted through a non-genotoxic threshold mode of action.

In 2004, the CTF submitted the results of the Peer Review Panel meeting to the EPA for review. EPA reviewed this information and determined that the weight of evidence indicates that captan's carcinogenicity is limited to a single tumor type (adenomas and adenocarcinomas in the small intestine, primarily the proximal portion of the duodenum) in both sexes of a single species (mouse). EPA agreed that the results of the rat bioassays provide no evidence that captan is associated with kidney tumors in male rats or uterine tumors in female rats, and, therefore, these tumors do not add to the weight-of-evidence considerations for the carcinogenicity of captan.

The Agency accepts the proposed mode of action as set forth by the CTF that suggests that ''captan induces adenomas and adenocarcinomas in the duodenum of the mouse by a non-genotoxic mode of action involving cytotoxicity and regenerative cell hyperplasia that exhibits a clear dose threshold. These responses are reversible following cessation of captan exposure. There is a strong causal association (dose-response, temporality) indicating that tumor formation is secondary to cytotoxicity and hyperplasia and that the latter is a key event in the sequential cascade of events leading to cancer.''

In September 2004, the Agency, in accordance with the EPA 1999 Proposed Guidelines for Carcinogen Risk Assessment, classified captan as ''not likely to be a human carcinogen at dose levels that do not cause cytotoxicity and regenerative cell hyperplasia'' and ''likely to be carcinogenic to humans following prolonged, high-level exposures causing cytotoxicity and regenerative cell hyperplasia.''

The new cancer classification considers captan to be a potential carcinogen at prolonged high doses that cause cytotoxicity and regenerative cell hyperplasia. These high doses of captan are many orders of magnitude above those likely to be consumed in the diet, or encountered by individuals in occupational or residential settings.

Therefore, captan is not likely to be a human carcinogen nor pose cancer risks of concern when used in accordance with approved product labels.

For further information and discussion about the cancer reclassification see the September 22, 2004 report, ''CAPTAN: Fourth Report of the Cancer Assessment Review Committee.'' In addition, the ''Reader's Guide to the Captan E-Docket'' provides an organized list to help readers navigate the documents in the docket, including scientific supporting documents and registrant and third-party submissions.

All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. Comments and proposals will become part of the Agency Docket for captan. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. EPA will carefully consider all comments received by the closing date and will provide a Response to Comments Memorandum in the Docket and electronic EDOCKET. If any comment significantly affects the document, EPA also will publish an amendment to the RED in the **Federal Register**. In the absence of substantive comments requiring changes, the captan RED will be implemented as it is now presented.

B. What is the Agency's Authority for Taking this Action?

Section 4(g)(2) of FIFRA, as amended, directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product specific data on individual end-use products and either reregistering products or taking other ''appropriate regulatory action.''

Section 408(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: November 12, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–26083 Filed 11–24–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0234; FRL–7370–8]

Cycloate; Availability of Reregistration Eligibility Decision Document for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces availability and starts a 60–day public comment period on the Reregistration Eligibility Decision (RED) document for the pesticide active ingredient cycloate (*S*-ethyl cyclohexyl(ethyl)thiocarbamate). The RED represents EPA's formal regulatory assessment of the health and environmental data base of the subject chemical and presents the Agency's determination regarding which pesticidal uses are eligible for reregistration.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0234, must be received on or before January 24, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–306–0327; e-mail address: *rodia.carmen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or the Federal Food, Drug, and Cosmetic Act (FFDCA); environmental, human health, and agricultural advocates; pesticides users; and members of the public interested in the use of pesticides. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0234. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Room 119, Crystal Mall #2, 1801 S. Bell Street, Arlington, VA 22202–4501. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. To access RED documents and RED fact sheets electronically, go directly to the REDs table on the EPA Office of Pesticide Programs Home Page, at *http://www.epa.gov/pesticides/reregistration/status.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA's Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA Dockets. EPA's policy is that copyrighted material will not be placed in EPA Dockets but will

be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA Dockets. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA Dockets. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA Dockets.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA Dockets as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA Dockets. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA Dockets. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA Dockets. Where practical, physical objects will be photographed, and the photograph will be placed in EPA Dockets along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA Dockets. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA Dockets to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0234. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0234. In contrast to EPA Dockets, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA Dockets, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA Dockets.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0234.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Room 119, Crystal Mall #2, 1801 S. Bell Street, Arlington, VA 22202–4501, Attention: Docket ID Number OPP–2004–0234. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA Dockets or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA Dockets. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA Dockets without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

The Agency has issued a RED for the pesticide active ingredient cycloate (*S*-ethyl cyclohexyl(ethyl)thiocarbamate) listed in this document. Under the FIFRA, as amended in 1988, EPA is conducting an accelerated reregistration program to reevaluate existing pesticides to make sure they meet current scientific and regulatory standards. The data base to support the reregistration of cycloate is substantially complete, and the pesticide's risks have been mitigated so that it will not pose unreasonable risks to people or the environment when used according to its approved labeling. In addition, EPA is reevaluating existing pesticides and reassessing tolerances under the Food Quality Protection Act (FQPA) of 1996. The pesticide included in this notice has been found to meet the FQPA safety standard.

The registrant of pesticide products containing the active ingredient cycloate will be sent a copy of the RED, and must respond to labeling requirements and product-specific data requirements (if applicable) within 8 months of receipt.

The reregistration program is being conducted under Congressionally mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing this RED as a final document with a 60–day comment period. Although the 60–day public comment period does not affect the registrant's response due date, it is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the RED. If any comment significantly affects the RED, EPA will amend the RED by publishing the amendment in the **Federal Register**.

B. What is the Agency's Authority for Taking this Action?

The legal authority for this RED falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product-specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: November 17, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–26084 Filed 11–23–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0265; FRL–7678–2]

Thiophanate-methyl; Availability of Reregistration Eligibility Decision Documents for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces availability and starts a 60–day public comment period on the Reregistration Eligibility Decision (RED) documents for the pesticide active ingredient thiophanate-methyl. The RED represents EPA's formal regulatory assessment of the health and environmental data base of the subject chemical and presents the Agency's determination regarding which pesticidal uses are eligible for reregistration.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0265, must be received on or before January 24, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Nathan Mottl, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0208; e-mail address: *mottl.nathan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or the Federal Food, Drug, and Cosmetic Act (FFDCA); environmental, human health, and agricultural advocates; pesticides users; and members of the public interested in the use of pesticides. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0265. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall#2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305 –5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. To access RED documents and RED fact sheets electronically, go directly to the REDs table on the EPA Office of Pesticide Programs Home Page, at *http://www.epa.gov/pesticides/reregistration/status.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets.

Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment, and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at*http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0265. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to*opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0265. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0265.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0265. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

The Agency has issued REDs for the pesticide active ingredient listed in this document. Under FIFRA, as amended in 1988, EPA is conducting an accelerated reregistration program to reevaluate existing pesticides to make sure they meet current scientific and regulatory standards. The data base to support the reregistration of the chemical listed in this document is substantially complete, and the pesticide's risks has been mitigated so that it will not pose unreasonable risks to people or the environment when used according to its approved labeling. In addition, EPA is reevaluating existing pesticides and reassessing tolerances under the Food Quality Protection Act (FQPA) of 1996. The pesticide included in this notice also has been found to meet the FQPA safety standard.

All registrants of pesticide products containing the active ingredient listed in this document have been sent the appropriate Data-Call-In, and must respond to labeling requirements and product-specific data requirements (if applicable) within 8 months of receipt. Products also containing other pesticide active ingredients will not be reregistered until those other active ingredients are determined to be eligible for reregistration.

The reregistration program is being conducted under Congressionally mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing the RED with a 60–day comment period. Although the 60–day public comment period does not affect the registrant's response due date, it is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the RED. After the comment period the Agency will write a response to comments memo, and will revise the RED as appropriate.

B. What is the Agency's Authority for Taking this Action?

The legal authority for these REDs falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product-specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: November 16, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–26082 Filed 11–24–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

[Report No. AUC–04–59–A; (Auction No. 59); DA 04–3198]

Multiple Address Systems Spectrum Auction; Reserve Prices or Minimum Opening Bids and Other Auction Procedures

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces the auction of 4,226 Multiple Address Systems (MAS) licenses in the Fixed Microwave Services from the 928/959 and 932/941 MHz bands scheduled to commence on April 26, 2005 (Auction No. 59). This document also seeks comment on reserve prices or minimum opening bids and other auction procedures for Auction No. 59.

DATES: Comments are due on or before December 2, 2004, and reply comments are due on or before December 9, 2004.

ADDRESSES: Comments and reply comments must be sent by electronic mail to the following address: *auction59@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: *For legal questions:* Howard Davenport, Auctions and Spectrum Access Division (202) 418–0660. *For general auction questions:* Roy Knowles or Barbara Sibert (717) 338–2888. *For service rule questions, contact the Public Safety and Critical Infrastructure Division, Wireless Telecommunications Bureau, as follows:* John Evanoff, (202) 418–0680; or Joan Howery, (717) 338–2646.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Public Notice released on November 15, 2004. The complete text of the *Auction No. 59 Comment Public Notice*, including attachments and of related Commission documents is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The *Auction No. 59 Comment Public Notice* and related Commission documents may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (''BCPI''), Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 202–488–5300, facsimile 202–488–5563, or you may contact BCPI at its Web site: *http://www.BCPIWEB.com* When ordering documents from BCPI, please provide the appropriate FCC document number (for example, FCC 00–313 for the C/F Block Sixth Report and Order). The *Auction No. 59 Comment Public Notice* and related documents are also available on the Internet at the Commission's Web site: *http://wireless.fcc.gov/auctions/59/*.

I. General Information

1. By the *Auction No. 59 Public Notice*, the Wireless Telecommunications Bureau (''Bureau'') announces the auction of 4,226 Multiple Address Systems (''MAS'') licenses in the Fixed Microwave Services from the 928/959 and 932/941 MHz bands to commence on April 26, 2005 (Auction No. 59). In Auction No. 59, licenses will be offered in each of the 176 geographic areas known as Economic Areas (EAs), where available. These geographic areas encompass the United States, Guam and the Northern Marianas Islands, Puerto Rico and the United States Virgin Islands, American Samoa, and the Gulf of Mexico. Due to the large number of licenses in Auction No. 59, the complete list of licenses available for this auction will be provided in electronic format

only, available as Attachment A of *Auction No. 59 Comment Public Notice.*

2. The following table contains the MAS block/frequency bands cross-reference list for Auction No. 59:

Block	Frequency bands* (MHz)	Total bandwidth**	Pairing	Geographic area type
AA	928.85625 / 959.85625	25 kHz	2 x 12.5 kHz	EA
AB	928.86875 / 959.86875	25 kHz	2 x 12.5 kHz	EA
AC	928.88125 / 959.88125	25 kHz	2 x 12.5 kHz	EA
AD	928.89375 / 959.89375	25 kHz	2 x 12.5 kHz	EA
AE	928.90625 / 959.90625	25 kHz	2 x 12.5 kHz	EA
AF	928.91875 / 959.91875	25 kHz	2 x 12.5 kHz	EA
AG	928.93125 / 959.93125	25 kHz	2 x 12.5 kHz	EA
AH	928.94375 / 959.94375	25 kHz	2 x 12.5 kHz	EA
AI	928.95625 / 959.95625	25 kHz	2 x 12.5 kHz	EA
AJ	928.96875 / 959.96875	25 kHz	2 x 12.5 kHz	EA
AK	928.98125 / 959.98125	25 kHz	2 x 12.5 kHz	EA
AL	928.99375 / 959.99375	25 kHz	2 x 12.5 kHz	EA
AM	932.00625 / 941.00625	25 kHz	2 x 12.5 kHz	EA
AN	932.01875 / 941.01875	25 kHz	2 x 12.5 kHz	EA
AO	932.03125 / 941.03125	25 kHz	2 x 12.5 kHz	EA
AP	932.04375 / 941.04375	25 kHz	2 x 12.5 kHz	EA
AQ	932.05625 / 941.05625	25 kHz	2 x 12.5 kHz	EA
AR	932.06875 / 941.06875	25 kHz	2 x 12.5 kHz	EA
AS	932.08125 / 941.08125	25 kHz	2 x 12.5 kHz	EA
AT	932.09375 / 941.09375	25 kHz	2 x 12.5 kHz	EA
AU	932.15625 / 941.15625	25 kHz	2 x 12.5 kHz	EA
AV	932.16875 / 941.16875	25 kHz	2 x 12.5 kHz	EA
AW	932.18125 / 941.18125	25 kHz	2 x 12.5 kHz	EA
AX	932.19375 / 941.19375	25 kHz	2 x 12.5 kHz	EA
AY	932.20625 / 941.20625	25 kHz	2 x 12.5 kHz	EA
AZ	932.21875 / 941.21875	25 kHz	2 x 12.5 kHz	EA
BA	932.23125 / 941.23125	25 kHz	2 x 12.5 kHz	EA
BB	932.24375 / 941.24375	25 kHz	2 x 12.5 kHz	EA

*The individual frequencies listed in this chart are the *center* frequencies of each frequency pair in the block to be auctioned. *See* 47 CFR 101.147(b)(3), (4). Each block consists of two channels of equal bandwidth. For example, in Block AA, 928.85625 and 959.85625 are the *center* frequencies and each frequency pair is comprised of two 12.5 kHz wide channels. Therefore, the two channels in Block AA are 928.8500–928.8625 MHz and 959.8500–959.8625 MHz.

**''Total Bandwidth'' represents the total bandwidth for the block, which is the combination of each channel in the pair.

Note: For Auction No. 59, licenses are not available in every block listed in the above table in every market. The complete list of licenses available for Auction No. 59 will be provided in electronic format only, available as Attachment A to the Auction No. 59 Comment Public Notice.

3. The Communications Act requires the Commission to ''ensure that, in the scheduling of any competitive bidding under this subsection, an adequate period is allowed * * * before issuance of bidding rules, to permit notice and comment on proposed auction procedures. * * *'' Consistent with the provisions of the Communications Act and to ensure that potential bidders have adequate time to familiarize themselves with the specific rules that will govern the day-to-day conduct of an auction, the Commission directed the Bureau, under its existing delegated authority, to seek comment on a variety of auction-specific procedures prior to the start of each auction. The Bureau therefore seeks comment on the following issues relating to Auction No. 59.

II. Auction Structure

A. Simultaneous Multiple-Round Auction Design

4. The Bureau proposes to award all licenses included in Auction No. 59 in a simultaneous multiple-round auction. As described further below, this methodology offers every license for bid at the same time with successive bidding rounds in which bidders may place bids. The Bureau seeks comment on this proposal.

B. Upfront Payments and Bidding Eligibility

5. The Bureau has delegated authority and discretion to determine an appropriate upfront payment for each license being auctioned, taking into account such factors as the population in each geographic license area and the value of similar spectrum. As described further below, the upfront payment is a refundable deposit made by each bidder to establish eligibility to bid on licenses. Upfront payments related to the specific spectrum subject to auction protect against frivolous or insincere bidding and provide the Commission with a source of funds from which to collect payments owed at the close of the auction. With these guidelines in mind for Auction No. 59, we propose to calculate upfront payments on a license-by-license basis using the following formula:

$0.00000375 * kHz * License Area Population with a minimum of $1,000 per license.

6. Accordingly, in Attachment A of the *Auction No. 59 Comment Public Notice* we list all licenses included in Auction No. 59 and the proposed upfront payment for each license. Attachment A of the *Auction No. 59 Comment Public Notice* is available in electronic format. The Bureau seeks comment on this proposal.

7. The Bureau further proposes that the amount of the upfront payment submitted by a bidder will determine the maximum number of bidding units on which a bidder may place bids. This limit is a bidder's initial eligibility. Each license is assigned a specific number of bidding units equal to the upfront payment listed in Attachment A of the *Auction No. 59 Comment Public Notice,* on a bidding unit per dollar basis. This number does not change as prices rise during the auction. A bidder's upfront payment is not attributed to specific

licenses. Rather, a bidder may place bids on any combination of licenses as long as the total number of bidding units associated with those licenses does not exceed its current eligibility. Eligibility cannot be increased during the auction. Thus, in calculating its upfront payment amount, an applicant must determine the maximum number of bidding units it may wish to bid on (or hold high bids on) in any single round, and submit an upfront payment covering that number of bidding units. The Bureau seeks comment on this proposal.

C. Activity Rules

8. In order to ensure that the auction closes within a reasonable period of time, an activity rule requires bidders to bid actively on a percentage of their current bidding eligibility during each round of the auction rather than waiting until the end to participate. A bidder that does not satisfy the activity rule will either lose bidding eligibility in the next round or must use an activity rule waiver (if any remain).

9. The Bureau proposes to divide the auction into two stages, each characterized by an increased activity requirement. The auction will start in Stage One. The Bureau proposes that the auction generally will advance from Stage One to Stage Two when the auction activity level, as measured by the percentage of bidding units receiving new high bids, is approximately twenty percent or below for three consecutive rounds of bidding. However, the Bureau further proposes that it retains the discretion to change stages unilaterally by announcement during the auction. In exercising this discretion, the Bureau will consider a variety of measures of bidder activity, including, but not limited to, the auction activity level, the percentage of licenses (as measured in bidding units) on which there are new bids, the number of new bids, and the percentage increase in revenue. The Bureau seeks comment on these proposals.

10. For Auction No. 59, we propose the following activity requirements:

Stage One: In each round of the first stage of the auction, a bidder desiring to maintain its current eligibility is required to be active on licenses representing at least 80 percent of its current bidding eligibility. Failure to maintain the requisite activity level will result in a reduction in the bidder's bidding eligibility in the next round of bidding (unless an activity rule waiver is used). During Stage One, reduced eligibility for the next round will be calculated by multiplying the current round activity by five-fourths (5/4).

Stage Two: In each round of the second stage, a bidder desiring to maintain its current eligibility is required to be active on 95 percent of its current bidding eligibility. In this final stage, reduced eligibility for the next round will be calculated by multiplying the current round activity by twenty-nineteenths (20/19).

11. The Bureau seeks comment on these proposals. Commenters that believe these activity rules should be modified should explain their reasoning and comment on the desirability of an alternative approach. Commenters are advised to support their claims with analyses and suggested alternative activity rules.

D. Activity Rule Waivers and Reducing Eligibility

12. Use of an activity rule waiver preserves the bidder's current bidding eligibility despite the bidder's activity in the current round being below the required minimum level. An activity rule waiver applies to an entire round of bidding and not to a particular license. Activity rule waivers can be either proactive or automatic and are principally a mechanism for auction participants to avoid the loss of auction eligibility in the event that exigent circumstances prevent them from placing a bid in a particular round.

Note: Once a proactive waiver is submitted, that waiver cannot be unsubmitted, even if the round has not yet closed.

13. The FCC Automated Auction System assumes that bidders with insufficient activity would prefer to use an activity rule waiver (if available) rather than lose bidding eligibility. Therefore, the system will automatically apply a waiver (known as an ''automatic waiver'') at the end of any bidding period where a bidder's activity level is below the minimum required unless: (i) there are no activity rule waivers available; or (ii) the bidder overrides the automatic application of a waiver by reducing eligibility, thereby meeting the minimum requirements.

Note: If a bidder has no waivers remaining and does not satisfy the required activity level, its current eligibility will be permanently reduced, possibly eliminating the bidder from the auction.

14. A bidder with insufficient activity may wish to reduce its bidding eligibility rather than use an activity rule waiver. If so, the bidder must affirmatively override the automatic waiver mechanism during the bidding period by using the ''reduce eligibility'' function in the bidding system. In this case, the bidder's eligibility is permanently reduced to bring the bidder into compliance with the activity rules as described above. Once eligibility has been reduced, a bidder will not be permitted to regain its lost bidding eligibility.

15. A bidder may proactively use an activity rule waiver as a means to keep the auction open without placing a bid. If a bidder submits a proactive waiver (using the proactive waiver function in the bidding system) during a bidding period in which no bids or withdrawals are submitted, the auction will remain open and the bidder's eligibility will be preserved. An automatic waiver invoked in a round in which there are no new valid bids or withdrawals will not keep the auction open.

16. The Bureau proposes that each bidder in Auction No. 59 be provided with three activity rule waivers that may be used at the bidder's discretion during the course of the auction as set forth above. The Bureau seeks comment on this proposal.

E. Information Relating to Auction Delay, Suspension, or Cancellation

17. For Auction No. 59, the Bureau proposes that, by public notice or by announcement during the auction, the Bureau may delay, suspend, or cancel the auction in the event of natural disaster, technical obstacle, evidence of an auction security breach, unlawful bidding activity, or administrative or weather necessity, or for any other reason that affects the fair and efficient conduct of competitive bidding. In such cases, the Bureau, in its sole discretion, may elect to resume the auction starting from the beginning of the current round, resume the auction starting from some previous round, or cancel the auction in its entirety. Network interruption may cause the Bureau to delay or suspend the auction. The Bureau emphasizes that exercise of this authority is solely within the discretion of the Bureau, and its use is not intended to be a substitute for situations in which bidders may wish to apply their activity rule waivers. The Bureau seeks comment on this proposal.

III. Bidding Procedures

A. Round Structure

18. The Commission will conduct Auction No. 59 over the Internet. Alternatively, telephonic bidding will also be available. The toll free telephone number through which telephonic bidding may be accessed will be announced in a later public notice. The FCC Wide Area Network will no longer be available as a contingency plan.

19. The initial bidding schedule will be announced in a public notice to be released at least one week before the start of the auction, and will be included in the registration mailings. The simultaneous multiple-round format will consist of sequential bidding rounds, each followed by the release of round results. Details regarding the location and format of round results will be included in the same public notice.

20. The Bureau has discretion to change the bidding schedule in order to foster an auction pace that reasonably balances speed with the bidders' need to study round results and adjust their bidding strategies. The Bureau may increase or decrease the amount of time for the bidding rounds and review periods, or the number of rounds per day, depending upon the bidding activity level and other factors. The Bureau seeks comment on this proposal.

B. Reserve Price or Minimum Opening Bid

21. The Communications Act calls upon the Commission to prescribe methods for establishing a reasonable reserve price or a minimum opening bid when FCC licenses are subject to auction, unless the Commission determines that a reserve price or minimum opening bid is not in the public interest. Consistent with this mandate, the Commission has directed the Bureau to seek comment on the use of a minimum opening bid and/or reserve price prior to the start of each auction.

22. Normally, a reserve price is an absolute minimum price below which an item will not be sold in a given auction. Reserve prices can be either published or unpublished. A minimum opening bid, on the other hand, is the minimum bid price set at the beginning of the auction below which no bids are accepted. It is generally used to accelerate the competitive bidding process. Also, the auctioneer often has the discretion to lower the minimum opening bid amount later in the auction. It is also possible for the minimum opening bid and the reserve price to be the same amount.

23. In light of the Communications Act's requirements, the Bureau proposes to establish minimum opening bids for Auction No. 59. The Bureau believes a minimum opening bid, which has been used in other auctions, is an effective bidding tool.

24. Specifically, for Auction No. 59, the Commission proposes the following license-by-license formula for calculating minimum opening bids: $0.00000375 * kHz * License Area Population with a minimum of $1,000 per license.

25. The specific minimum opening bid for each license available in Auction No. 59 is set forth in Attachment A of *Auction No. 59 Comment Public Notice.* The Bureau seeks comment on this proposal.

26. If commenters believe that these minimum opening bids will result in substantial numbers of ''unwon'' licenses, or are not reasonable amounts, or should instead operate as reserve prices, they should explain why this is so, and comment on the desirability of an alternative approach. Commenters are advised to support their claims with valuation analyses and suggested reserve prices or minimum opening bid levels or formulas. In establishing the minimum opening bids, the Bureau particularly seeks comment on such factors as the amount of spectrum being auctioned, levels of incumbency, the availability of technology to provide service, the size of the geographic service areas, issues of interference with other spectrum bands and any other relevant factors that could reasonably have an impact on valuation of these MAS licenses. The Bureau also seeks comment on whether, consistent with the Communications Act, the public interest would be served by having no minimum opening bid or reserve price.

C. Minimum Acceptable Bids and Bid Increments

27. In each round, eligible bidders will be able to place bids on a given license in any of nine different amounts. The FCC Automated Auction System interface will list the nine acceptable bid amounts for each license. Until a bid has been placed on a license, the minimum acceptable bid for that license will be equal to its minimum opening bid. In the rounds after a bid is placed on a license, the minimum acceptable bid for that license will be equal to the standing high bid plus the defined increment.

28. Once there is a standing high bid on a license, the FCC Automated Auction System will calculate a minimum acceptable bid for that license for the following round, as described below. The difference between the minimum acceptable bid and the standing high bid for each license will define the bid increment. The nine acceptable bid amounts for each license consist of the minimum acceptable bid (the standing high bid plus one bid increment) and additional amounts calculated using multiple bid increments (*i.e.*, the second bid amount equals the standing high bid plus two times the bid increment, the third bid amount equals the standing high bid plus three times the bid increment, etc.).

29. For Auction No. 59, the Bureau proposes to use a 10 percent bid increment. This means that the minimum acceptable bid for a license will be approximately 10 percent greater than the previous standing high bid received on the license. The minimum acceptable bid amount will be calculated by multiplying the standing high bid times one plus the increment percentage ''*i.e.*, (standing high bid) * (1.10). The Commission will round the result using our standard rounding procedures for minimum acceptable bid calculations: results above $10,000 are rounded to the nearest $1,000; results below $10,000 but above $1,000 are rounded to the nearest $100; and results below $1,000 are rounded to the nearest $10.

30. As stated above, until a bid has been placed on a license, the minimum acceptable bid for that license will be equal to its minimum opening bid. The additional bid amounts are calculated using the difference between the minimum opening bid times one plus the minimum percentage increment, rounded as described above, and the minimum opening bid. That is, I = (minimum opening bid)(1 + N){rounded} − (minimum opening bid). Therefore, when N equals 0.1, the first additional bid amount will be approximately ten percent higher than the minimum opening bid; the second, twenty percent; the third, thirty percent; etc.

31. In the case of a license for which the standing high bid has been withdrawn, the minimum acceptable bid will equal the second highest bid received for the license. The additional bid amounts are calculated using the difference between the second highest bid times one plus the minimum percentage increment, rounded, and the second highest bid.

32. The Bureau retains the discretion to change the minimum acceptable bids and bid increments if it determines that circumstances so dictate. The Bureau will do so by announcement in the Automated Auction System. The Bureau seeks comment on these proposals.

D. High Bids

33. At the end of a bidding round, a high bid for each license will be determined based on the highest gross bid amount received for the license. In the event of identical high bids on a license in a given round (*i.e.*, tied bids), we propose to use a random number generator to select a single high bid from among the tied bids. If the auction were

to end with no higher bids being placed for that license, the winning bidder would be the one that placed the selected high bid. However, the remaining bidders, as well as the high bidder, can submit higher bids in subsequent rounds. If any bids are received on the license in a subsequent round, the high bid again will be determined by the highest gross bid amount received for the license. The Bureau seeks comment on this proposal.

34. A high bid will remain the high bid until there is a higher bid on the same license at the close of a subsequent round. A high bid from a previous round is sometimes referred to as a ''standing high bid.'' Bidders are reminded that standing high bids count towards bidding activity.

E. Information Regarding Bid Withdrawal and Bid Removal

35. For Auction No. 59, the Bureau proposes the following bid removal and bid withdrawal procedures. Before the close of a bidding period, a bidder has the option of removing any bid placed in that round. By removing selected bids in the bidding system, a bidder may effectively ''unsubmit'' any bid placed within that round. A bidder removing a bid placed in the same round is not subject to a withdrawal payment. Once a round closes, a bidder may no longer remove a bid.

36. A high bidder may withdraw its standing high bids from previous rounds using the withdraw function in the bidding system. A high bidder that withdraws its standing high bid from a previous round is subject to the bid withdrawal payment provisions of the Commission rules. The Bureau seeks comment on these bid removal and bid withdrawal procedures.

37. In the *Part 1 Third Report and Order*, 63 FR 770, January 7, 1998, the Commission explained that allowing bid withdrawals facilitates efficient aggregation of licenses and the pursuit of efficient backup strategies as information becomes available during the course of an auction. The Commission noted, however, that, in some instances, bidders may seek to withdraw bids for improper reasons. The Bureau, therefore, has discretion, in managing the auction, to limit the number of withdrawals to prevent any bidding abuses. The Commission stated that the Bureau should assertively exercise its discretion, consider limiting the number of rounds in which bidders may withdraw bids, and prevent bidders from bidding on a particular market if the Bureau finds that a bidder is abusing the Commission's bid withdrawal procedures.

38. Applying this reasoning, the Bureau proposes to limit each bidder in Auction No. 59 to withdrawing standing high bids in no more than two rounds during the course of the auction. To permit a bidder to withdraw bids in more than two rounds would likely encourage insincere bidding or the use of withdrawals for anti-competitive purposes. The two rounds in which withdrawals are utilized will be at the bidder's discretion; withdrawals otherwise must be in accordance with the Commission's rules. There is no limit on the number of standing high bids that may be withdrawn in either of the rounds in which withdrawals are utilized. Withdrawals will remain subject to the bid withdrawal payment provisions specified in the Commission's rules. The Bureau seeks comment on this proposal.

F. Stopping Rule

39. The Bureau has discretion to establish stopping rules before or during multiple round auctions in order to terminate the auction within a reasonable time. For Auction No. 59, the Bureau proposes to employ a simultaneous stopping rule approach. A simultaneous stopping rule means that all licenses remain available for bidding until bidding closes simultaneously on all licenses.

40. Bidding will close simultaneously on all licenses after the first round in which no new bids, proactive waivers, or withdrawals are received. Thus, unless circumstances dictate otherwise, bidding will remain open on all licenses until bidding stops on every license.

41. However, the Bureau proposes to retain the discretion to exercise any of the following options during Auction No. 59:

i. Utilize a modified version of the simultaneous stopping rule. The modified stopping rule would close the auction for all licenses after the first round in which no bidder submits a proactive waiver, withdrawal, or a new bid on any license on which it is not the standing high bidder. Thus, absent any other bidding activity, a bidder placing a new bid on a license for which it is the standing high bidder would not keep the auction open under this modified stopping rule. The Bureau further seeks comment on whether this modified stopping rule should be used at any time or only in stage two of the auction.

ii. Keep the auction open even if no new bids or proactive waivers are submitted and no previous high bids are withdrawn. In this event, the effect will be the same as if a bidder had submitted a proactive waiver. The activity rule, therefore, will apply as usual and a bidder with insufficient activity will either lose bidding eligibility or use a remaining activity rule waiver.

iii. Declare that the auction will end after a specified number of additional rounds (''special stopping rule''). If the Bureau invokes this special stopping rule, it will accept bids in the specified final round(s) only for licenses on which the high bid increased in at least one of a specified preceding number of rounds.

42. The Bureau proposes to exercise these options only in certain circumstances, for example, where the auction is proceeding very slowly, there is minimal overall bidding activity, or it appears likely that the auction will not close within a reasonable period of time. Before exercising these options, the Bureau is likely to attempt to increase the pace of the auction by, for example, increasing the number of bidding rounds per day, and/or increasing the amount of the minimum bid increments for the limited number of licenses where there is still a high level of bidding activity. The Bureau seeks comment on these proposals.

IV. Conclusion

43. Comments are due on or before December 2, 2004, and reply comments are due on or before December 9, 2004. Because of the disruption of regular mail and other deliveries in Washington, DC, the Bureau requires that all comments and reply comments be filed electronically. Comments and reply comments must be sent by electronic mail to the following address: *auction59@fcc.gov*. The electronic mail containing the comments or reply comments must include a subject or caption referring to Auction No. 59 Comments and the name of the commenting party. The Bureau requests that parties format any attachments to electronic mail as Adobe® Acrobat® (pdf) or Microsoft® Word documents. Copies of comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Information Center, Room CY–B402, 445 12th Street, SW., Washington, DC 20554. In addition, the Bureau requests that commenters fax a courtesy copy of their comments and reply comments to the attention of Kathryn Garland at (717) 338–2850.

44. This proceeding has been designated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain

summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. Other rules pertaining to oral and written ex parte presentations in permit-but-disclose proceedings are set forth in § 1.1206(b) of the Commission's rules.

Federal Communications Commission.

Gary D. Michaels,

Deputy Chief, Auctions and Spectrum Access Division, WTB.

[FR Doc. 04–26061 Filed 11–23–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

PREVIOUSLY ANNOUNCED DAY AND TIME: Tuesday, November 16, 2004, 10 a.m. Meeting Closed to the Public. This meeting was cancelled.

DATE AND TIME: Tuesday, November 30, 2004 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. section 437g, section 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, December 2, 2004 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Draft Advisory Opinion 2004–40: The Libertarian Party of Maryland by Joseph J. Miller, Treasurer.

Notice of Proposed Rulemaking on Party Donations to Tax-exempt Organizations.

Routine Administrative Matters.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Biersack, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 04–26199 Filed 11–22–04; 2:49 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may obtain copies of agreements by contacting the Commission's Office of Agreements at 202–523–5793 or via e-mail at *tradeanalysis@fmc.gov*. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011324–016.

Title: Transpacific Space Utilization Agreement.

Parties: American President Lines Ltd.; APL Co. Pte Ltd.; Evergreen Marine Corporation (Taiwan), Ltd.; Hanjin Shipping Co., Ltd.; Hapag-Lloyd Container Linie GmbH; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; P&O Nedlloyd, Ltd.; P&O Nedlloyd B.V.; Westwood Shipping Lines; and Yangming Marine Transport Corp.

Filing Party: Wayne R. Rohde, Esq., Sher & Blackwell, 1850 M Street, NW., Suite 900, Washington, DC 20036.

Synopsis: The amendment deletes A.P. Moller-Maersk Sealand as a party to the agreement.

Agreement No.: 011852–014.

Title: Maritime Security Discussion Agreement.

Parties: China Shipping Container Lines, Co., Ltd.; CMA CGM, S.A.; COSCO Container Lines Company, Ltd.; Evergreen Marine Corp.; Hanjin Shipping Company, Ltd.; Hapag Lloyd Container Linie GmbH; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; P&O Nedlloyd Limited; Yang Ming Marine Transport Corp.; Zim Integrated Shipping Services, Ltd.; Alabama State Port Authority; APM Terminals North America, Inc.; Ceres Terminals, Inc.; Cooper/T. Smith Stevedoring Co., Inc.; Global Terminal & Container Services, Inc.; Howland Hook Container Terminal, Inc.; Husky Terminal & Stevedoring, Inc.; International Shipping Agency; International Transportation Service, Inc.; Lambert's Point Docks Inc.; Long Beach Container Terminal, Inc.; Maersk Pacific Ltd.; Maher Terminals, Inc.; Marine Terminals Corp.; Maryland Port Administration; Massachusetts Port Authority; Metropolitan Stevedore Co.; P&O Ports North American, Inc.; Port of Tacoma; South Carolina State Ports Authority; Stevedoring Services of America, Inc.; Trans Bay Container Terminal, Inc.; TraPac Terminals; Universal Maritime Service Corp.; Virginia International Terminals; and Yusen Terminals, Inc.

Filing Parties: Carol N. Lambos, Lambos & Junge, 29 Broadway, 9th Floor, New York, NY 10006 and Charles T. Carroll, Jr., Carroll & Froelich, PLLC, 2011 Pennsylvania Avenue, NW., Suite 301, Washington, DC 20006.

Synopsis: The amendment deletes Eagle Marine Services, Ltd. as a member to the agreement.

Dated: November 19, 2004.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 04–26064 Filed 11–23–04; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR part 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel-Operating Common Carrier Ocean Transportation Intermediary Applicants:

Westcove Investments, Inc. dba Cargo Link International, 1810 Borrego Drive, West Covina, CA 91791. Officers: Rey Nicolas Dumandan, President/CEO (Qualifying Individual), Maria Lourdes A. Timbol, Secretary.

Seagold (USA) Inc., 219 Stuyvesant Avenue, Lyndhurst, NY 07071. Officer: Tariq Mahmood, President (Qualifying Individual).

Trans Freight (USA) Inc., 317 W. Main Street, Unit 419, Alhambra, CA 91801. Officer: Sammy Jing Huang, President (Qualifying Individual).

Nelcon Cargo Corporation, 179 Morningside Drive, Miami Springs, FL 33166. Officers: Nydia Bermudez, President (Qualifying Individual), Estela Perez, Vice President.

Dispatch Logistics Services Logistics Air Limited, 3744 Industry Avenue, Suite 404, Lakewood, CA 90712. Officers: Carla Yuen-Yi Leung, Vice President (Qualifying Individual), Leung Lai Kin, Director.

Non-Vessel—Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants:

Xima Freight Services, Inc., 8217 NW 66th Street, Miami, FL 33166. Officers: Xiomara L. Salazar, Vice President (Qualifying Individual), Maite Avila, President.

D.B. Group America, Ltd., 182–17 150th Avenue, 2nd Floor, Jamaica, NY 11413. Officers: Gian Mario Favalli, Assistant Treasurer (Qualifying Individual), Vittorino De Bortoli, President.

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants:

USA Cargo & Courier Inc., 5900 NW 97th Avenue, Unit C1 & C2, Miami, FL 33178. Officers: Heriberto Sanchez, Ocean Manager (Qualifying Individual), Alexander Moreno, President.

A & A International Shipping Inc., 333 N. Marine Avenue, Wilmington, CA 90744. Officers: Algis Gulbinas, President (Qualifying Individual), Anton Tombu, CEO.

Dated: November 19, 2004.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 04–26065 Filed 11–23–04; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the State Children's Health Insurance Program, and Aid To Needy Aged, Blind, or Disabled Persons for October 1, 2005 Through September 30, 2006

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice.

SUMMARY: The Federal Medical Assistance Percentages and Enhanced Federal Medical Assistance Percentages for Fiscal Year 2006 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2005 through September 30, 2006. This notice announces the calculated ''Federal Medical Assistance Percentages'' and ''Enhanced Federal Medical Assistance Percentages'' that we will use in determining the amount of Federal matching for State medical assistance (Medicaid) and State Children's Health Insurance Program (SCHIP) expenditures, and Temporary Assistance for Needy Families (TANF) Contingency Funds, the federal share of Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Foster Care Title IV–E Maintenance payments, and Adoption Assistance payments. The table gives figures for each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. Programs under title XIX of the Act exist in each jurisdiction; programs under titles I, X, and XIV operate only in Guam and the Virgin Islands; while a program under title XVI (Aid to the Aged, Blind, or Disabled) operates only in Puerto Rico. Programs under title XXI began operating in fiscal year 1998. The percentages in this notice apply to State expenditures for most medical services and medical insurance services, and assistance payments for certain social services. The statute provides separately for Federal matching of administrative costs.

Sections 1905(b) and 1101(a)(8)(B) of the Act require the Secretary of Health and Human Services to publish the Federal Medical Assistance Percentages each year. The Secretary is to figure the percentages, by formulas in sections 1905(b) and 1101(a)(8)(B), from the Department of Commerce's statistics of average income per person in each State and in the Nation as a whole. The percentages are within the upper and lower limits given in section 1905(b) of the Act. The percentages to be applied to the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands are specified in statute, and thus are not based on the statutory formula that determines the percentages for the 50 states.

The ''Federal Medical Assistance Percentages'' are for Medicaid. Section 1905(b) of the Act specifies the formula for calculating Federal Medical Assistance Percentages as follows:

''Federal medical assistance percentage'' for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 50 per centum.

A provision in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 modified the formula to calculate the percentages to be applied to Alaska for purposes of titles XIX and XXI of the Act for fiscal years 2001 through 2005. For Alaska only, the formula required dividing the state's three-year average per capita income by 1.05 instead of 1.0. This provision has not been extended, and therefore the calculation for Alaska reverts to the standard formula.

In addition, section 4725 of the Balanced Budget Act of 1997 amended section 1905(b) to provide that the Federal Medical Assistance Percentage for the District of Columbia for purposes of titles XIX and XXI shall be 70 percent. For the District of Columbia, we note under the table of Federal Medical Assistance Percentages the rate that applies in certain other programs calculated using the formula otherwise applicable, and the rate that applies in certain other programs pursuant to section 1118 of the Social Security Act.

Section 2105(b) of the Act specifies the formula for calculating the Enhanced Federal Medical Assistance Percentages as follows:

The ''enhanced FMAP'', for a State for a fiscal year, is equal to the Federal medical assistance percentage (as defined in the first sentence of section 1905(b)) for the State increased by a number of percentage points equal to 30 percent of the number of percentage points by which (1) such Federal medical assistance percentage for the State, is less than (2) 100 percent; but in no case shall the enhanced FMAP for a State exceed 85 percent.

The ''Enhanced Federal Medical Assistance Percentages'' are for use in the State Children's Health Insurance Program under Title XXI, and in the Medicaid program for certain children for expenditures for medical assistance described in sections 1905(u)(2) and 1905(u)(3) of the Act. There is no specific requirement to publish the Enhanced Federal Medical Assistance Percentages. We include them in this notice for the convenience of the States.

DATES: The percentages listed will be effective for each of the 4 quarter-year periods in the period beginning October 1, 2005 and ending September 30, 2006.

FOR FURTHER INFORMATION CONTACT: Carrie Becker or Robert Stewart, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D—Hubert H. Humphrey

Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690–6870.

(Catalog of Federal Domestic Assistance Program Nos. 93.558: TANF Contingency Funds; 93.563: Child Support Enforcement; 93–596: Child Care Mandatory and Matching Funds of the Child Care and Development Fund; 93.658: Foster Care Title IV–E; 93.659: Adoption Assistance; 93.769: Ticket-to-Work and Work Incentives Improvement Act (TWWIIA) Demonstrations to Maintain Independence and Employment; 93.778: Medical Assistance Program; 93.767: State Children's Health Insurance Program)

Dated: November 18, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

Federal medical assistance percentages and enhanced Federal medical assistance percentages, Effective October 1, 2005-September 30, 2006 (Fiscal year 2006)

State	Federal Medical Assistance Percentages	Enhanced Federal Medical Assistance Percentages
Alabama	69.51	78.66
Alaska	50.16	65.11
American Samoa*	50.00	65.00
Arizona	66.98	76.89
Arkansas	73.77	81.64
California	50.00	65.00
Colorado	50.00	65.00
Connecticut	50.00	65.00
Delaware	50.09	65.06
District of Columbia**	70.00	79.00
Florida	58.89	71.22
Georgia	60.60	72.42
Guam*	50.00	65.00
Hawaii	58.81	71.17
Idaho	69.91	78.94
Illinois	50.00	65.00
Indiana	62.98	74.09
Iowa	63.61	74.53
Kansas	60.41	72.29
Kentucky	69.26	78.48
Louisiana	69.79	78.85
Maine	62.90	74.03
Maryland	50.00	65.00
Massachusetts	50.00	65.00
Michigan	56.59	69.61
Minnesota	50.00	65.00
Mississippi	76.00	83.20
Missouri	61.93	73.35
Montana	70.54	79.38
Nebraska	59.68	71.78
Nevada	54.76	68.33
New Hampshire	50.00	65.00
New Jersey	50.00	65.00
New Mexico	71.15	79.81
New York	50.00	65.00
North Carolina	63.49	74.44
North Dakota	65.85	76.10
Northern Mariana Islands*	50.00	65.00
Ohio	59.88	71.92
Oklahoma	67.91	77.54
Oregon	61.57	73.10
Pennsylvania	55.05	68.54
Puerto Rico*	50.00	65.00
Rhode Island	54.45	68.12
South Carolina	69.32	78.52
South Dakota	65.07	75.55
Tennessee	63.99	74.79
Texas	60.66	72.46
Utah	70.76	79.53
Vermont	58.49	70.94
Virgin Islands*	50.00	65.00
Virginia	50.00	65.00
Washington	50.00	65.00
West Virginia	72.99	81.09
Wisconsin	57.65	70.36
Wyoming	54.23	67.96

* For purposes of section 1118 of the Social Security Act, the percentage used under titles I, X, XIV, and XVI will be 75 per centum.

** The values for the District of Columbia in the table were set for the state plan under titles XIX and XXI and for capitation payments and DSH allotments under those titles. For other purposes, including programs remaining in Title IV of the Act, the percentage for D.C is 50.00.

[FR Doc. 04–26056 Filed 11–23–04; 8:45 am]
BILLING CODE 4510–24–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0106]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–498–1210 or send comments to Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Preventive Health and Health Services Block Grant, Annual Application and Reports, OMB No. 0920–0106–Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and brief description:

In 1994, OMB approved the collection of information provided in the grant applications and annual reports for the Preventive Health and Health Services (PHHS) Block Grant (OMB No. 0920–0106). This approval expires on January 31, 2005. CDC is requesting OMB clearance for this legislatively mandated information collection until January 31, 2008. The request is to approve the development and adherence to *Healthy People 2010* (the Nation's Health Objectives) which was released in the Spring of 2000. The PHHS block grant is mandated according to section 1904 to adhere to the Healthy People framework.

This information, which is collected through the application forms from the official State health agencies, is required from section 1905 of the Public Health Service Act. There is a slight change in the proposed information collection from previous years. The changes include more program specific information and the relationship of block funded activities to program strategy. The information collected from the annual report forms is required by section 1906. The development of a PHHS block grant web page, with data web links from existing federal databases, will be used to coincide with the collection of uniform data for the annual report. The availability to collect data through internet accessibility will allow for a more streamlined and efficient use of data processing by the states and reduce the states' burden of duplicate reporting on outcome and risk factor data. There is no cost to respondents except their time to complete the application/report.

ANNUALIZED BURDEN TABLE

Forms	No. of respondents	No. of responses/respondent	Average burden per response in hours	Total burden
Annual applications	*61	1	30	1830
Annual reports	61	1	40	2440
Total				4270

*There are 61 respondents (Official State Health Agencies from the 50 States, the District of Columbia, 8 U.S. Territories, and two American Indian Tribes (Santee Sioux and Kickapoo of Kansas). The response burden consists of an annual application and an annual report (with selected summary data items).

Dated: November 12, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–26020 Filed 11–23–04; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0260]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–498–1210 or send comments to Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)

ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Health Hazard Evaluation/Technical Assistance and Emerging Problems (OMB No. 0920–0260)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Each year, in accordance with its mandates under the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977, the National Institute for Occupational Safety and Health (NIOSH) responds to approximately 450 requests for health hazard evaluations to identify potential chemical, biological or physical hazards at the workplace. To comprehensively evaluate hazards in response to a request for a health hazard evaluation, NIOSH frequently conducts an on-site evaluation. The main purpose of an on-site evaluation is to help employers and employees identify and eliminate occupational health hazards. The interview and questionnaires are specific to each workplace and its suspected diseases(s) and hazards. The questionnaires are composed of items that were developed from standard medical and epidemiologic techniques.

A printed NIOSH form is available in English and in Spanish for requesting these health hazard evaluations. The form is also available on the Internet and differs from the printed version only in format and in the fact that it uses an Internet address to which recipients can submit the form to NIOSH. Both the printed and Internet versions of the form provide the mechanism for employees, employers, and other authorized representatives to supply the information required by the regulations which govern the NIOSH health hazard evaluation program (42 CFR 85.3–1). In general, if employees are submitting the form it must contain the signatures of three or more current employees. However, regulations allow a single signature if the requestor is one of three or fewer employees in the process, operation, or job of concern. The form for requesting a health hazard evaluation is currently approved by OMB under the information collection 0920–0102, ''Contents of a Request for a Health Hazard Evaluation.'' CDC would like to merge the form approved under 0920–0102 into 0920–0260, ''Health Hazard Evaluation/Technical Assistance and Emerging Problems.'' This would consolidate two data collection systems into one.

The information provided on the Request for a Health Hazard Evaluation form is used by NIOSH to determine whether there is reasonable cause to justify conducting an investigation. Without the information requested on this form, NIOSH would be unable to perform its legislated function of conducting health hazard evaluations in workplaces. There is no cost to respondents to obtain this form or to request a health hazard evaluation, except their time in completing the form. The additional burden for the Request for Health Hazard Evaluation form is 90 hours per year.

ANNUALIZED BURDEN TABLE

Respondents	No. of respondents	No. of responses per respondent	Avg. burden per response (in hrs.)	Total burden hours
Employees and representatives	290	1	12/60	58
Employers	160	1	12/60	32
Total	450			90

Dated: November 12, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–26021 Filed 11–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05AF]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–498–1210 or send comments to Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

How Miners Modify Their Behavior In Response To Personal Dust Monitor Information—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

The Federal Mine Safety and Health Act of 1977, section 501, enables CDC/NIOSH to carry out research relevant to the health and safety of workers in the mining industry. The objective of this project is to document how coal miners can use real-time information from their personal dust monitors (PDM) to reduce their exposure to respirable dust. The specific aims are to (1) identify several specific examples of how miners use PDM information to discover which parts of their jobs and/or which aspects of their work environment may be causing them to be overexposed to

respirable dust, and (2) identify the types of changes that miners could make in order to try to reduce their exposure. Although the most recent data on the prevalence of Coal Workers' Pneumoconiosis (CWP) in the United States indicates that it is declining, substantial numbers of CWP cases continue to be diagnosed. In recent years, CWP has contributed to the deaths of approximately 1,000 people in the U.S. each year.

A personal dust monitor (PDM) has recently been developed through a collaboration involving NIOSH, the Bituminous Coal Operators' Association, the United Mine Workers of America, the National Mining Association, and Rupprecht & Patashnick Co., Inc. This new device represents a major advance in the tools available for assessing coal miners' exposure to respirable dust levels. It will soon be field tested with coal miners throughout the U.S. As with the introduction of any new technology, it is very important to systematically document how workers react to it and make use of it. If miners know how to properly use the information PDMs are capable of providing, they should be able to make adjustments to their work place or work procedures that will reduce their exposure to respirable coal dust.

Various parties have speculated about the processes by which miners will use the information to reduce their exposure to respirable dust. There appears to be great potential. However, no one knows precisely how miners performing a wide variety of tasks and jobs are actually going to use this new information to reduce their exposure to dust. It is assumed that, once PDMs are introduced, miners will eventually find new ways to reduce their exposure to dust. Once these discoveries are made, they need to be documented and shared throughout the industry. The diffusion of this innovation will occur much more rapidly and efficiently if this proposed study takes place. Effective strategies for using PDM information will be well documented and quickly shared throughout the coal industry. The alternative is to wait for the miners at each of the 439 actively producing coal mines in the U.S. to go through their own trial and error process of discovering how PDMs can and cannot be used to reduce dust exposure. The proposed study will help to significantly reduce the incidence of lung disease among coal miners, leading to improvements in their longevity and quality of life. The information for this study will be collected by conducting one-on-one structured interviews with approximately 20 miners at each of 5 mines located throughout the major coal producing regions of the U.S. This survey will last 2 years. There will be no cost to respondents except their time to participate.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Coal Miners	100	1	30/60	50
Total				50

Dated: November 17, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–26022 Filed 11–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–0212]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–498–1210 or send comments to Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

National Hospital Discharge Survey (OMB No. 0920–0212)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

The National Hospital Discharge Survey (NHDS) has been conducted continuously by CDC, National Center for Health Statistics since 1965. It is the principal source of data on inpatient utilization of short-stay, non-Federal hospitals and is the only annual source of nationally representative estimates on the characteristics of discharges, the lengths of stay, diagnoses, surgical and non-surgical procedures, and the patterns of use of care in hospitals in various regions of the country. It is the benchmark against which special programmatic data sources are compared. Data collected through the NHDS are essential for evaluating the health status of the population, planning of programs and policy to elevate the health status of the Nation, studying morbidity trends, and research activities in the health field. NHDS data have been used extensively in the development and monitoring of goals for the Year 2000 and 2010 Health Objectives. In addition, NHDS data provide annual updates for numerous tables in the Congressionally-mandated NCHS report, Health, United States.

Data for the NHDS are collected annually on approximately 300,000 discharges from a nationally representative sample of noninstitutional hospitals exclusive of Federal, military and Veterans' Administration hospitals. The data items collected are the basic core of

variables contained in the Uniform Hospital Discharge Data Set (UHDDS) in addition to two data items (admission type and source) which are identical to those needed for billing of inpatient services for Medicare patients. In the 2003 NHDS, 426 hospitals participated. Data for approximately forty-four percent of the responding hospitals (186) are abstracted from medical records. The remaining hospitals supply data through in-house tapes or printouts (80 hospitals) or are hospitals that belong to commercial abstract service organizations or state data systems (160 hospitals) from which electronic data files are purchased. There is no actual cost to respondents since hospital staff who actively participate in the data collection effort are compensated by the government for their time.

Medical record abstracts	Number of respondents (hospitals)	Number of responses/ respondent	Average burden/response (in hrs.)	Total burden hours
Primary Procedure Hospitals	62	250	5/60	1,292
Alternate Procedure Hospitals	124	250	1/60	517
In-House Tape or Printout Hospitals	80	12	12/60	192
Induction Forms	15	1	2	30
Non-response Study	50	1	2	100
Total				2,131

Dated: November 12, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–26023 Filed 11–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05AH]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–498–1210 or send comments to Sandi Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

A Comprehensive Evaluation of an Approach to Self-Management: ''Diabetes: Living My Best Life''—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description: African-American women are more than twice as likely as white women to be diagnosed with diabetes, and two and one-half times as likely to die from diabetic complications. The onset of type 2 diabetes in African-American adults is attributable not only to a genetic link, but also to an unhealthy lifestyle. The vast number of African-American women with type 2 diabetes report having a sedentary lifestyle and eating a diet high in fat. In addition to taking medications, lifestyle modifications, such as changes in diet, weight loss and participating in a low-impact exercise program, can significantly reduce the complications experienced by women with type 2 diabetes. Unfortunately, there is a scarcity of training and educational materials on type 2 diabetes targeting the African-American woman. The limited availability of targeted educational materials has undoubtedly contributed to an inability to manage and control this disease in this population and has resulted in a higher prevalence of disease-related co-morbidities. There is a need for innovative interventions that can be used in a variety of settings and which feature culturally appropriate information that will engage African-American women with type 2 diabetes in a proactive role in the treatment and management of their disease.

The proposed project is the evaluation of a CD–ROM educational program: ''Diabetes: Living My Best Life.'' This product has been developed to teach African American women with type 2 diabetes self-management skills. Social Learning Theory (SLT) was used in the development of the product and the selection of the media elements. Selection of the information and tools was guided by input from an advisory board composed of professionals in the field and African American women with type 2 diabetes.

To evaluate this program there will be two questionnaires: a pre-test and a post-test. The two questionnaires will include questions on:

- Respondent demographic information (pre-test only).
- Respondent use of computers (pre-test only).
- Knowledge of diabetes.
- Self-efficacy in addressing diabetes self-management issues.
- Diabetes self-care activities.
- Feeling of empowerment around diabetes self-management.
- Social learning theory elements (post-test only).

Pre and post intervention data will be collected by computer. Burden estimates are based on observation of African-American women with type 2 diabetes who completed a formal pilot test of the pre and post-test forms. There are no costs to respondents except their time to participate in the survey.

ANNUALIZED BURDEN TABLE

Respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
African American women with Type 2 diabetes—Pre-test	66	1	20/60	22
African American women with Type 2 diabetes—Posttest	66	1	20/60	22
Total				44

Dated: November 18, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–26024 Filed 11–23–04; 8:45 am]

BILLING CODE 4163—18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Refugee Resettlement Program Estimates: CMA, ORR–1.

OMB No.: 0970–0030.

Description: The Office of Refugee Resettlement (ORR) reimburses, to the extent of available appropriations, certain non-Federal costs for the provision of cash and medical assistance to refugees, along with allowable expenses in the administration of the Refugee Resettlement Program. ORR needs sound State estimates of likely expenditures for refugee cash, medical, and administrative (CMA) expenditures so that it can anticipate Federal costs in upcoming quarters. If Federal costs are anticipated to exceed budget allocations, ORR must take steps to reduce Federal expenses, such as limiting the number of months of eligibility for Refugee Cash Assistance and Refugee Medical Assistance.

To meet the need for reliable State estimates of anticipated expenses, ORR has developed a single-page form in which States estimate the average number of recipients for each category of assistance, the average unit cost over the next 12 months, and the expense for the overall administration of the program. This form, the ORR–1, must be submitted prior to the beginning of each Federal fiscal year. Without this information, ORR would be out of compliance with the intent of its legislation and otherwise unable to estimate program costs adequately.

In addition, the ORR–1 serves as the State's application for reimbursement of its CMA expenses. Submission of this form is thus required by section 412(a)(4) of the Immigration and Nationality Act, which provides that ''no grant or contract may be awarded under this section unless an appropriate proposal and application * * * are submitted to, and approved by, the appropriate administering official.''

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1	48	1	.5	24

Estimated Total Annual Burden Hours: 24.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, *Katherine_T._Astrich@omb.eop.gov*.

Dated: November 17, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–25991 Filed 11–23–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities.

OMB No.: 0980–0270.

Description: As required by Federal statute and regulation, each State Protection and Advocacy System must prepare and submit to public comment a Statement of Goals and Priorities (SGP). The final version of this SGP for the coming fiscal year is submitted to the Administration on Developmental Disabilities (ADD). The information in the SGP will be aggregated into a national prospective profile of where Protection and Advocacy Systems are going. It will provide ADD with a tool for monitoring the public input requirement. Further, it will provide an overview of program direction, and permit ADD to track accomplishments against goals/targets, permitting the formulation of technical assistance and

compliance with the Government Performance and Results Act.

Respondents: State and Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SGP	57	1	44	2,508

Estimated Total Annual Burden Hours: 2,508.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 17, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–25992 Filed 11–23–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National Medical Support Notice.

OMB No.: 0970–0222.

Description: The information collected by state IV–D child support enforcement agencies is used to complete the National Medical Support Notice (NMSV) that is sent to employers of employee/obligors and used as a means of enforcing the health care coverage provision in a child support order. Primarily, the information the state child support enforcement agencies use to complete the NMSN is information regarding appropriate persons that is necessary for the enrollment of the child in employment-related health care coverage, such as the employee/obligor's name, address, and Social Security number; the employer's name and address; the name and address of the alternate recipient (child); the custodial parent's name and address. The employer forwards the second part of the NMSN to the group health plan administrator, which contains the same individual identifying information. The plan administrator requires this information to determine whether to enroll the alternate recipient in the group health plan. If necessary, the employer also initiates withholding from the employee's wages for the purpose of paying premiums to the group health plan for enrollment of the child.

Respondents: State and local title IV–D child support enforcement agencies initiate the process of enforcing medical health care coverage for the child by completing and sending the notice to known employers of the noncustodial parents (employee/obligor). Employers and plan administrators are on the receiving end of the notice.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45CFR303.32	54	13,454	.17	123,507

Estimated Total Annual Burden Hours: 123,507.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB received it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-Mail address: *Katherine_T._Astrich@omb.eop.gov*.

Dated: November 17, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–25993 Filed 11–23–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Child Care Report for High Performance Bonus.

OMB No.: 0970–0255.

Description: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. 104–193, established the Temporary Assistance for Needy Families (TANF) program under title IV–A of the Social Security Act (the Act), 42 U.S.C. 401 *et seq.* Section 403(a)(4) of the Act requires the Secretary to award bonuses to ''high performing States.'' (Indian tribes are not eligible for these bonuses.) The term ''high performing States'' is defined in section 403(a)(4) of the Act to mean a State that is most successful in achieving the purposes of the TANF program as specified in section 401(a) of the Act.

The final rule covering the TANF high performance bonuses to States in FY 2002 and beyond was published August 30, 2000 (65 FR 52814) followed by an interim final rule published May 10, 2001 (66 FR 23854). The final and interim final rules set forth how the Child Care Bureau (CCB) will compute scores and rank States won the three components, *i.e.*, Accessibility, Affordability, and Quality, that comprise the child care measure.

In FY 2002, CCB measured State performance on a composite ranking of two components, *i.e.*, Accessibility and Affordability (based on FY 2001 performance data). No additional reporting burden was required since the data/information for the Accessibility and Affordability components are reported under the Child Care Development Fund program (ACF Reports 800 and 801). However, there was a reporting burden (related to the Quality component) for the information States submitted if they wished to compete on the child care measure beginning in FY 2003 and again in FY 2004 (based on FY 2002 and FY 2003 performance data, respectively). The same requirements must be met for States wishing to compete on the child care measure for FY 2005 (based on FY 2004 performance data). The information includes:

(1) All age-specific rates for children 0–13 years of age reported by the child day care centers and family day care homes responding to the State's market rate survey; and

(2) The provider's county or, if the State uses multi-county regions to measure market rates or set maximum payment rates, the administrative region.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	0.5	40	1,120

Estimated Total Annual Burden Hours. 1,120.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 17, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–25994 Filed 11–23–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0503]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Consultation Procedures; Foods Derived From New Plant Varieties

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the Guidance on Consultation Procedures; Foods Derived From New Plant Varieties.

DATES: Submit written or electronic comments on the collection of information by January 24, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.

1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance on Consultation Procedures; Foods Derived From New Plant Varieties

Since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties (the 1992 policy) (57 FR 22984, May 29, 1992), FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, FDA explained that, under the Federal Food, Drug, and Cosmetic Act (the act), developers of new foods (in this document food refers to both human food and animal feed) have a responsibility to ensure that the foods they offer to consumers are safe and are in compliance with all requirements of the act (57 FR 22984 at 22985).

FDA has long regarded it to be a prudent practice for producers who use biotechnology in the manufacture or development of foods and food ingredients to work cooperatively with FDA to ensure that products derived through biotechnology are safe and comply with all applicable legal requirements. Consequently, FDA instituted a voluntary consultation process with industry. The Guidance on Consultation Procedures; Foods Derived From New Plant Varieties (Originally published in 1996 and revised October 1997, the updated version is available on FDA's Internet site at *http://www.cfsan.fda.gov/~lrd/consulpr.html*) fosters communication by encouraging developers to submit to FDA their evaluation of the food safety of their new plant variety. Such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development, and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the act.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Initial consultation	20	2	40	4	160
Final consultation	12	1	12	150	1,800
Annual one time burden hours					1,960

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

A. Initial Consultations

Initial consultations are generally a one-time burden, although a developer might return more than once to discuss additional issues before submitting a final consultation. As noted in its guidance to industry, FDA encourages developers to consult early in the development phase of their products, and as often as necessary. Historically, the food industry generally has initiated consultation with FDA early in the process of developing a new bioengineered plant variety, even though there is no legal obligation to do so. These consultations have served to make FDA aware of foods and food ingredients before these products are distributed commercially, and have provided FDA with the information necessary to address any potential questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the agency in exercising their mutual responsibilities under the act.

Generally, for an initial consultation, a developer requests a meeting by sending FDA a letter with an agenda. A mutually convenient time is arranged and the developer comes to discuss their product. In preparation for a meeting, a developer might prepare written materials or a slide presentation to discuss their product under development. A meeting between the developer and FDA typically lasts between 1 and 2 hours. As a result of such a meeting, FDA establishes a file called a biotechnology notification file, or BNF, to collect all documentation and communication regarding the bioengineered plant.

Depending on the introduced trait, the experience the developer has had with the kind of modification being considered, and their familiarity with the consultation procedures, a developer might choose to do a final consultation without an initial consultation.

B. Final Consultations

Final consultations are a one-time burden. At some stage in the process of research and development, a developer will have accumulated the information that the developer believes is adequate to ensure that food derived from the new plant variety is safe and that it demonstrates compliance with the relevant provisions of the act. The developer will then be in a position to conclude any ongoing consultation with FDA. The developer submits to FDA a summary of the safety and nutritional assessment that has been conducted about the bioengineered food that is intended to be introduced into commercial distribution. FDA evaluates the submission to ensure that all potential safety and regulatory questions have been addressed.

Summary information of the safety and nutritional assessment for a new plant variety submitted to FDA includes the following information:

- The name of the bioengineered food and the crop from which it is derived;
- A description of the various applications or uses of the bioengineered food, including animal feed uses;
- Information concerning the sources, identities, and functions of introduced genetic material;
- Information on the purpose or intended technical effect of the modification, and its expected effect on the composition or characteristic properties of the food or feed;
- Information concerning the identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or food derived therefrom;
- Information regarding any known or suspected allergenicity and toxicity of expression products and the basis for concluding that foods containing the expression products can be safely consumed;
- Information comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties of the same crop with special emphasis on important nutrients, and toxicants that occur naturally in the food;
- A discussion of the available information that addresses whether the potential for the food derived from a bioengineered plant to induce an allergic response has been altered by the genetic modification; and
- Any other information relevant to the safety and nutritional assessment of the bioengineered food.

In 2001 FDA contacted five firms that had made one or more biotechnology consultation submissions under the 1996 procedures. FDA asked each of these firms for an estimate of the hourly burden to prepare a submission under the voluntary biotechnology consultation process. Three of these firms subsequently provided the requested information. Based on this information, FDA is estimating that the average time to prepare a submission for final consultation under the 1996 procedures is 150 hours.

Dated: November 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26048 Filed 11–19–04; 1:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0369]

Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.'' The draft guidance, when finalized, is intended to provide recommendations to developers of new plant varieties, in particular bioengineered plants, on the early food safety evaluation of new non-pesticidal proteins. The draft guidance describes procedures for submitting an early food safety evaluation of such proteins to the agency.

DATES: Submit written or electronic comments concerning the draft guidance and the collection of information provisions by January 24, 2005.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' to Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1165. Send one self-adhesive address label to assist that office in processing your request, or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments concerning the draft guidance and the collection of information provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1165, FAX 301–436–2965, e-mail: *mditto@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In a document in the **Federal Register** of August 2, 2002 (67 FR 50578), the U.S. Office of Science and Technology Policy (OSTP) proposed Federal actions to update field test requirements and to establish early voluntary food safety evaluations for new proteins produced by bioengineered plants. Rapid developments in genomics are resulting in dramatic changes in the way new plant varieties are developed and commercialized. Scientific advances are expected to accelerate over the next decade, leading to the development and commercialization of a greater number and diversity of bioengineered crops. As the number and diversity of field tests for bioengineered plants increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced during field tests with commercial seeds or grain may also increase. This could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated through FDA's voluntary consultation procedures for foods derived from new plant varieties (referred to as ''biotechnology consultation'' in the case of bioengineered plants).[1] FDA is issuing a draft guidance document to address this possibility.

This draft guidance describes the procedure for early food safety evaluation of new proteins produced by new plant varieties that are under

[1] Guidance on Consultation Procedures: Foods Derived from New Plant Varieties can be found at *http://www.cfsan.fda.gov/~lrd/consulpr.html*.

development. While this guidance is focused on new proteins in bioengineered plants, these procedures may, of course, be used for new proteins in non-bioengineered foods as well. This draft guidance also provides information to sponsors and developers about submitting their evaluation to FDA.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on the early food safety assessment of new proteins produced by new plant varieties intended for food use. It does not create or confer any rights, for or on any person, and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing the guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed in the title page of the guidance.

II. Paperwork Reduction Act of 1995

This draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Elsewhere, in this issue of the **Federal Register**, FDA is publishing a notice announcing an opportunity for public comment on the information collection, entitled ''Guidance on Consultation Procedures; Foods Derived from New Plant Varieties.''

Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

Since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties (57 FR 22984, May 29, 1992), FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA early in the development process to discuss possible scientific and regulatory issues that might arise. The current guidance continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety.

FDA believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. This guidance describes the procedures for early food safety evaluation of new proteins in new plant varieties, including bioengineered food plants, and the procedures for communicating with FDA about the safety evaluation.

Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

TABLE 1.—ESTIMATED REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Operating and Maintenance Costs	Total Hours
First four data components	20	1	20	4	$0	80
Two other data components	20	1	20	16	$0	320
Annual one-time burden hours						400

[1] There are no capital costs or operating or maintenance costs associated with this collection of information.

Burden:

Hour Burden Estimate

One Time Burden

Completing an early food safety evaluation for a new protein from a new plant variety will be a one-time burden (one evaluation per new protein). FDA cannot know how many developers will choose to complete an early food safety evaluation for their new plant protein. Some plant developers may choose not to complete an evaluation because of the uncertainty of the new plant variety's future viability in the marketplace. Other developers may have previously communicated with FDA about the food safety of a new protein, for example, when the same protein was expressed in a different crop. Still other developers may test a new plant variety under such

conditions that those developers have no concerns that the new protein could enter the food supply.

FDA scientists predict that this draft guidance will generate about 20 to 150 early food safety evaluations yearly. While there is uncertainty as to the number of developers who will choose to submit an evaluation, FDA estimates that the annual number of early food safety evaluations will be closer to the lower bound estimate of 20 evaluations rather than the upper bound estimate of 150 evaluations. This estimation is supported by the fact that on average there have been nine initial biotechnology consultations per year; an initial biotechnology consultation has traditionally been the first discussion between a developer and FDA about a bioengineered food.

Evaluation Components

The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. FDA estimates that completing these data components will take about 4 hours per evaluation. In table 1 of this document, row 1 shows that for 20 evaluations, the total burden for these 4 data components is 80 hours.

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves 'wet' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study).

The paperwork burden of these two data components consists of the time it takes the company to put together the information on these two data components to submit to FDA. We estimate that these two data components will take 16 hours to complete (8 hours for each component). Table 1, row 2, shows that for 20 evaluations, the total burden for these two data components is 320 hours.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance and the collection of information provisions. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the draft guidance is available on the Internet at *http://www.cfsan.fda.gov/guidance.html* and *http://www.fda.gov/cvm*.

Dated: November 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26049 Filed 11–19–04; 1:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0481]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry.'' This guidance document describes a means by which newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry may comply with the requirements of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry into class II (special controls). This guidance document is immediately in effect as the special control for newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidances are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol C. Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, ext. 144.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying newborn screening test systems for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for newborn screening test systems for amino acids, free carnitine, and acylcarnitines that utilize tandem mass spectrometry. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving written notice classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1)

of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device.

Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on newborn screening test systems for amino acids, free carnitine, and acylcarnitines that utilize tandem mass spectrometry. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry'' by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1301) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–25976 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0479]

Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and is requesting comment on, a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The veterinary drug of interest in this risk assessment is the streptogramin, virginiamycin, a drug approved for use in chicken, turkey, swine, and cattle feed. FDA will consider information received during the comment period in its preparation of a final risk assessment.

DATES: Submit written or electronic comments on the draft risk assessment document by January 24, 2005. FDA will accept comments, data, and information after the deadline, but to assure consideration by the agency, we must receive comments by this date.

ADDRESSES: Single copies of this draft risk assessment are available from the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Please enclose a self-addressed, adhesive label to assist that office in processing your request. This draft risk assessment is also available on the Internet at: *http://www.fda.gov/cvm/antimicrobial/antimicrobial.htm*.

Send written comments on this draft risk assessment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*.

FOR FURTHER INFORMATION CONTACT: Barry Hooberman, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8557, e-mail: *bhooberm@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 19, 2000 (65 FR 20992), FDA's Center for Veterinary Medicine (CVM) announced plans to develop a prototypic risk assessment (RA) model that accounts for the transfer of resistance determinants from bacteria in food-producing animals to bacteria in humans. CVM also requested comments on their approach to the RA model, requested that scientific data and information relevant to the conduct of the RA be submitted, and indicated its intention to work with stakeholders to assess potential risks.

The outcome of our work is a document entitled ''Draft Risk Assessment of Streptogramin Resistance in *Enterococcus faecium* Attributable to the Use of Streptogramins in Animals.'' This draft risk assessment specifically addresses the link between the use of the streptogramin antimicrobial, virginiamycin, in food-producing animals and the development of resistance to the related streptogramins, quinupristin-dalfopristin, used to treat human enterococcal infections. Enterococcus bacteria include commensal strains normally present in the intestines of animals and man. This risk assessment focuses on the opportunistic pathogen *Enterococcus faecium*.

In an effort to better ensure broad awareness of this **Federal Register** notice, FDA will make copies available through the FDA Dockets Listserv (*http://www.fda.gov/ohrms/dockets/FDAMAIL/DMBemaillist.htm*). To be added to any of FDA's free e-mail subscription services go to: *http://www.fda.gov*. Click on ''Subscribe to FDA's E-mail Lists'', then follow the instructions provided.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25979 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Testing Advisory Board to be held in December 2004.

On December 7, the Board will meet in an open session from 8:30 a.m. to 9:30 a.m. The open session will include a Department of Health and Human Services drug testing program update, a Department of Transportation drug testing program update, and a Nuclear Regulatory Commission drug testing program update. Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

The Board will also meet in closed sessions on December 7 from 9:30 a.m. to 4:30 p.m. and on December 8 from 8:30 a.m. until noon to develop the analytical and administrative policies for the final Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program that were published as proposed revisions in the **Federal Register** on April 13, 2004 (69 FR 19673). The submissions from 285 commenters have been made available to the public on the Web site *http://workplace.samhsa.gov.* This portion of the meeting must be conducted in closed sessions since discussing such public comments in an open session and then developing the policies will significantly frustrate the Department's ability to develop the Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The HHS Office of General Counsel made the determination that such matters are protected by exemption 9(B) of section 552b(c) of title 5 U.S.C. and therefore may be closed to the public.

A roster of the board members may be obtained from: Mrs. Giselle Hersh, Division of Workplace Programs, 1 Choke Cherry Road, Room 2–1035, Rockville, MD 20857, 240–276–2600 (telephone). The transcript of the open session will be available on the following Web site: *http://workplace.samhsa.gov.* Additional information for this meeting may be obtained by contacting the individual listed below.

Committee Name: Substance Abuse and Mental Health Services, Administration Drug Testing Advisory Board.

Meeting Date: December 7, 2004; 8:30 a.m.–4:30 p.m., December 8, 2004; 8:30 a.m.–Noon.

Place: Residence Inn by Marriott, 7335 Wisconsin Avenue, Bethesda, Maryland 20814.

Type: Open: December 7, 2004; 8:30 a.m.–9:30 a.m., *Closed:* December 7, 2004; 9:30 a.m.–4:30 p.m., *Closed:* December 8, 2004; 8:30 a.m.–Noon.

Contact: Donna M. Bush, Ph.D., Executive Secretary, 1 Choke Cherry Road, Room 2–1035, Rockville, Maryland 20857, Email: *Donna.Bush@samhsa.hhs.gov*, 240–276–2600 (telephone) or 240–276–2610 (fax).

Dated: November 15, 2004.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 04–26025 Filed 11–23–04; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2004–0023]

Homeland Security Advisory Council

AGENCY: Office of the Secretary, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will hold a meeting for purposes of (1) receiving reports from Senior Advisory Committees; (2) receiving briefings from DHS staff on Departmental initiatives; and (3) holding roundtable deliberations and discussions among HSAC members.

DATES: The Homeland Security Advisory Council (HSAC) will hold its next meeting in San Diego, CA on Tuesday, December 14, 2004.

ADDRESSES: This meeting will be partially closed; the open portions of the meeting for purposes of (1) above will be held at the Westin Horton Plaza Hotel Library, 910 Broadway Circle, San Diego, CA 92101 from 9:30 a.m. to 11:30 a.m. The closed portions of the meeting, for purposes of (2) and (3) above will be held at the Westin Horton Plaza Hotel Harbor Room, 910 Broadway Circle, San Diego, CA 92101 from 8:30 a.m. to 9:20 a.m. and from 11:30 a.m. to 3:30 p.m.

You may submit comments, identified by DHS–2004–0023, by *one* of the following methods:

- EPA Federal Partner EDOCKET Web site: *http://www.epa.gov/feddocket.* Follow instructions for submitting comments on the Web site. The Department of Homeland Security has joined the Environmental Protection Agency (EPA) online public docket and comment system on its Partner Electronic Docket System (Partner EDOCKET). The Department of Homeland Security and its agencies (excluding the United States Coast Guard and Transportation Security Administration) will use the EPA Federal Partner EDOCKET system. The USCG and TSA [legacy Department of Transportation (DOT) agencies] will continue to use the DOT Docket Management System until full migration to the electronic rulemaking federal docket management system in 2005.
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *HSAC@dhs.gov.* Include docket number in the subject line of the message.
- Fax: (202) 772–9718.
- Mail: Mike Miron, Homeland Security Advisory Council, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *www.epa.gov/feddocket,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.epa.gov/feddocket.* You may also access the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information concerning the meeting, please contact Rich Davis, Jeff Gaynor, Mike Miron, or Candice Stoltz of the HSAC staff via email at *HSAC@dhs.gov,* or via phone at 202–692–4283.

SUPPLEMENTARY INFORMATION:

Public Attendance: A limited number of members of the public may register to attend the public session on a first-come, first-served basis per the procedures that follow. Security requires that any member of the public who wishes to attend the public session provide his or her name, social security number, and date of birth no later than 5 p.m., EST, Tuesday, December 7, 2004 to the Responsible Agency Officials (listed above) via email at *HSAC@dhs.gov,* or via phone at (202) 692–4283. Persons with disabilities who require special assistance should indicate so in their admittance request and are encouraged to indicate their desires to attend as early as possible. Photo identification will be required for entry into the public session, and everyone in attendance must be present and seated by 9:15 a.m.

Basis for Closure: In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App. 2), the Secretary has issued a determination that portions of this HSAC meeting will concern matters sensitive to homeland security within the meaning of 5 U.S.C. 552b(c)(7) and (c)(9)(B) and that, accordingly, these portions of the meeting will be closed to the public.

Dated: November 18, 2004.

Tom Ridge,

Secretary of Homeland Security.

[FR Doc. 04–26057 Filed 11–23–04; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Renewal Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; OMB Control Number 1018–0102; Special Use Permit Applications on National Wildlife Refuges Outside Alaska Covering 50 CFR 25.41, 25.61, 26.36, 27.71, 27.91, 27.97, 29.1, 29.2, 30.11, 31.2, 31.13, 31.14, 31.16, and 43 CFR 5

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Fish and Wildlife Service (We) is requesting that OMB extend an existing approval to collect information for Special Use Permit Applications on Refuges Outside Alaska. We will use the information that we collect to determine if requested activities are compatible and appropriate with the purpose for which the refuge was established.

DATES: You must submit comments on or before December 27, 2004.

ADDRESSES: Send your comments on this information collection renewal to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–6566 (fax) or at *OIRA_DOCKET@OMB.eop.gov* (e-mail). Please provide a copy of your comments to Hope Grey, Information Collection Clearance Officer, Fish and Wildlife Service, 4401 N. Fairfax Drive, MS 222–ARLSQ, Arlington, Virginia 22203 (mail); (703) 358–2269 (fax); or *hope_grey@fws.gov* (e-mail).

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection requirement, explanatory information, or related forms, contact Hope Grey at the address or fax number listed above or by telephone at (703) 358–2482.

SUPPLEMENTARY INFORMATION: We have sent a request to OMB to renew approval of the information collection requirements for Special Use Permit Applications on National Wildlife Refuges Outside of Alaska. Currently we have approval from OMB to collect information under OMB control number 1018–0102. This approval expires on November 30, 2004. We may not conduct or sponsor, and a person is not required to respond to, a collection of information unless we display a currently valid OMB control number. OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (*see* CFR 1380.8(d)). OMB has up to 60 days to approve or disapprove our information collection request, but their response may be given as early as 30 days after our submittal. Therefore, to ensure consideration, send your comments to OMB by the date listed in the **DATES** section near the beginning of this notice.

On July 16, 2004, we published in the **Federal Register** (69 FR 42762) a 60-day notice of our intent to request renewal of this information collection authority from OMB. In that notice, we solicited public comments for 60 days ending September 14, 2004. We received three comments regarding this notice.

Comment: A commenter felt that (1) the proposal was too vague and we should describe what kind of permits we issue; (2) at an estimate of 25 permits issued per refuge, we were issuing too many permits; and (3) farming activities were incompatible with refuge operations.

Response: (1) The universe of types of permits potentially issued on our 529 national wildlife refuges outside of Alaska prevents us from listing each and every type of permit. We describe a sampling of the types of permits a refuge manager, upon finding an activity compatible, might issue. (2) As to the average estimate of permits issued per refuge, each refuge manager must decide

on the merits of a request using various methods of determination, such as compatibility, funding and other resource availability to ensure adequate protection of refuge resources and the visiting public, etc., before issuing a Special Use Permit. (3) Again, the refuge manager may determine that, in some cases, farming activities are a management tool that may answer the criteria outlined in answer (2) and are compatible with the purpose for which their particular refuge was established.

Comment: We received two comments from ham radio operators that disagreed with the decision by the refuge manager to deny issuance of a permit for the purpose of receiving and broadcasting transmissions. The requestors felt this request was not incompatible with the purposes for which the refuge was established.

Response: The purpose of this notice was to solicit comments on information collection requirements for Special Use Permit applications in the National Wildlife Refuge System. These comments relate not to the purpose of the notice itself, but rather to the compatibility decisionmaking process whereby a refuge manager decides whether or not to allow a public use on a national wildlife refuge. Because these comments are not substantive to the purpose of this notice and this is not the appropriate venue for the commenters to resolve their concerns, we will not address those concerns in this forum.

Comment: We received a comment that suggested that the Special Use Permit application be made available online for potential permittees to download themselves and fill out to cut down on ''hard paper'' and facilitate electronic issuance of the permits.

Response: We have considered electronic access to and processing of Special Use Permits. However, for the purposes of proper management oversight, control, and enforcement of permit condition violations (*e.g.*, original signature on permit application), and ensuring local conditions are considered as part of each request, we elect at this time to continue with the existing local paper system. However, during this renewal period, we will be studying the feasibility of separating the application from the permit and making the application available online for electronic submission.

The National Wildlife Refuge System Improvement Act of 1997 that amends the National Wildlife Refuge Administration Act of 1966 (16 U.S.C. 668dd–668ee) requires that we authorize economic privileges on any national wildlife refuge by permit only when the activity will be compatible with and contribute to refuge purposes (50 CFR 29.21). We will provide the permit applications as requested by interested citizens. We will use information provided on the required written forms and verbal explanatory information to ensure that the applicant is eligible for the permit. We make provision in our general refuge regulations for public entry for specialized purposes, including economic activities such as the operation of guiding and other visitor services on refuges by concessionaires or cooperators under the appropriate legal instrument or special use permits (50 CFR 25.41, 25.61, 26.36, 27.71, 27.91, 27.97, 29.1, 29.2, 30.11, 31.2, 31.13, 31.14, 31.16, and 43 CFR 5). These regulations provide the authorities and procedures for allowing permits on refuges outside of Alaska.

We will use this permit to authorize such items as farming operations (haying and grazing, 50 CFR 29.2), beneficial management tools that we use to provide the best habitat possible on some refuges (50 CFR 30.11, 31.14, 31.16), recreational visitor service operations (50 CFR 25.41 and 25.61), commercial filming (50 CFR 27.71), other commercial activities (50 CFR 29.1), research, and other noncommercial activities (50 CFR 26.36). We will issue permits for a specific period as determined by the type and location of the use or visitor service provided.

Title: Special Use Permit Applications on National Wildlife Refuges Outside Alaska.

OMB Control Number: 1018–0102.

Form Number: 3–1383.

Frequency of Collection: On occasion.

Description of Respondents: Individuals and households; business and other for-profit organizations; nonprofit institutions; farms; and State, local or tribal governments.

Total Annual Responses: 14,150. We have 529 national wildlife refuges and 37 wetland management districts outside the State of Alaska. We anticipate that each unit will authorize approximately 25 permits each year.

Total Annual Burden: 14,150 hours.

Your comments are invited on: (1) Whether or not this collection of information is necessary for us to properly perform our functions, including whether or not this information will have practical utility; (2) the accuracy of our estimates of burden, including the validity of the methodology and assumptions we use; (3) ways to enhance the quality, utility, and clarity of the information we are proposing to collect; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the record, which we will honor to the extent allowable by law. If you wish us to withhold your name and/or address, you must state this clearly at the beginning of your comment. We will not consider anonymous comments. We generally make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: November 5, 2004.

Hope Grey,

Information Collection Clearance Officer, Fish and Wildlife Service.

[FR Doc. 04–25899 Filed 11–23–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–310–1310–PB–24 1A]

OMB Control Number 1004–0196; Information Collection Submitted to the Office of Management and Budget Under the Paperwork Reduction Act

The Bureau of Land Management (BLM) has submitted an extension of a currently approved collection to collect the information listed below to the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). On February 10, 2003, the BLM published a notice in the **Federal Register** (68 FR 6757) requesting comment on this information collection. The comment period ended on April 11, 2003. The BLM received no comments. You may obtain copies of the collection of information and related forms and explanatory material by contacting the BLM Information Collection Clearance Officer at the telephone number listed below.

The OMB must respond to this request within 60 days but may respond after 30 days. For maximum consideration your comments and suggestions on the requirements should be directed within 30 days to the Office

of Management and Budget, Interior Department Desk Officer (1004–0196), at OMB–OIRA via facsimile to (202) 396–6566 or e-mail to *OIRA_DOCKET@omb.eop.gov*. Please provide a copy of your comments to the Bureau Information Collection Clearance Officer (WO–630), Bureau of Land Management, Eastern States Office, 7450 Boston Blvd., Springfield, Virginia 22153.

Nature of Comments: We specifically request your comments on the following:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;

2. The accuracy of our estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;

3. The quality, utility and clarity of the information we collect; and

4. How to minimize the burden of collecting the information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Title: Oil and Gas Leasing: National Petroleum Reserve, Alaska (NPRA) (43 CFR 3130, 3133, 3135, 3137, 3138, 3160).

OMB Control Number: 1004–0196.

Bureau Form Number: Nonform.

Abstract: The BLM uses the information from oil and gas operators and operating rights owners to maintain records or provide information to apply for suspensions of royalty; apply for suspensions of operations; form and maintain unit agreements; and to enter into subsurface storage agreements.

Frequency: Occasional

Description of Respondents: Oil and gas operators and operating rights owners.

ESTIMATED COMPLETION TIME

Information collection (43 CFR)	Requirement	Hours per response	Number of respondents	Total burden hours
3133.4	Royalty reduction	16	1	16
3135.3	Suspension of operations	4	1	4
3135.6	Notification of operations	.25	1	.25
3137.23	Unit designation	80	3	240
3137.25	Notification of unit approval	1	3	3
3137.52	Certification for modification	4	1	4
3137.60	Acceptable Bonding	.5	3	1.5
3137.61	Change of unit operator	.75	2	1.5
3137.70	Certification of unit obligation	2	3	6
3137.71	Certification of continuing development	2	3	6
3137.84	Productivity for a PA	12	2	24
3137.87	Unleased tracts	3	1	3
3137.88	Notification of productivity	.5	1	.5
3137.91	Notification of productivity for non-unit well	.5	1	.5
3137.92	Production information	1	1	1
3137.112	Lease extension	3	1	3
3137.113	Inability to conduct operations activities	2	2	2
3137.130	Unit termination	1	2	2
3137.135	Impact mitigation	4	3	12
3138.11	Storage agreement	80	1	80
Totals			35	410.25

Annual Responses: 35.

Application Fee Per Response. $0.

[FR Doc. 04–25997 Filed 11–23–04; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–220–1020–PB–24 1A]

Extension of Approved Information Collection OMB Control Number 1004–0041

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) will be requesting the Office of Management and Budget (OMB) to extend an existing approval to collect certain information from permittees and lessees on the actual grazing use by their livestock. BLM requires permittees or lessees to submit the required information on Forms 4130–1, 4130–1a, 4130–1b, 43130–3a, 4130–4, and 4130–5 under the regulations at 43 CFR subparts 4110 and 4130.

DATES: You must submit your comments to BLM at the address below on or before January 24, 2005. BLM will not necessarily consider any comments received after the above date.

ADDRESSES: You may mail comments to: Bureau of Land Management, (WO–630), Eastern States Office, 7450 Boston Blvd., Springfield, Virginia 22153.

You may send comments via Internet to: *WOComment@blm.gov.* Please include ''ATTN 1004–0041'' and your name and return address in your Internet message.

You may deliver comments to the Bureau of Land Management, Administrative Record, Room 401, 1620L Street, NW., Washington, DC.

All comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15 p.m.), Monday through Friday except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ken Visser, on (775) 861–6492 (Commercial or FTS). Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) on 1–800–877–8330, 24 hours a day, seven days a week, to contact Mr. Visser.

SUPPLEMENTARY INFORMATION:

Title: Authorizing Grazing Use (43 CFR 4110 and 4130).

OMB Control Number: 1004–0041.

Abstract: This request for OMB approval is intended to cover all

information collection in Part 4130, both form and non-form.

5 CFR 1320.12(a) requires that we provide a 60-day notice in the **Federal Register** concerning a collection of information to solicit comments on:

(1) Whether the collection information of information is necessary for the proper functioning of the agency, including whether the information will have practical utility;

(2) The accuracy of our estimates of the information collection burden, including the validity of the methodology and assumptions we use;

(3) Ways to enhance the quality, utility, and clarity of the information collected; and respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

The Taylor Grazing Act of 1934 (43 U.S.C. 315, 315a through 315r) and the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*) authorize the Bureau of Land Management (BLM) to administer the livestock grazing program consistent with land use plans, multiple us objectives, sustained yield, environmental values, economic considerations, and other factors. BLM must maintain accurate records on:

(1) Permittee and lessee qualifications for a grazing permit or lease;

(2) Base property used in conjunction with public lands; and

(3) The actual use made by livestock authorized to graze on the public lands.

Form 4130–1, Grazing Schedule

BLM uses the required information on this form to adjudicate conflicting requests for grazing use, determine legal qualifications of applicants, issue permits, and document transfers.

Form 4130–1a, Grazing Application—Preference Summary

BLM uses from 4130–1a to verify and confirm information BLM needs to effectuate a grazing preference transfer.

Form 4130–1b, Grazing Application (Supplemental Information)

BLM uses the required information on this form to certify an applicant's qualifications for a grazing permit or lease and to provide other information necessary for the administration of the grazing permit or lease.

Form 4130–3a. Automated Grazing Application

BLM uses the required information on this form to approve changes of grazing use within the terms and conditions of permits or leases.

Form 4130–4, Exchange of Use Grazing Agreement

BLM uses this form to exchange grazing of livestock on private lands during certain periods.

Form 4130–5, Actual Grazing Use Report

BLM uses the required information to determine if we need to adjust the amount of grazing use or if other management actions are needed. This form enables us to calculate billings and to monitor and evaluate livestock grazing use on the public lands.

The burden estimates for each form are listed as follows:

Forms	4130–1	4130–1a	4130–1b	4130–3a	4130–4	4130–5
Annual Number of Responses filed	6,000	6,000	6,000	7,689	600	15,000
Average Response Time	[1] 20	[1] 15	[1] 15	[1] 14	[1] 20	[1] 25
Annual Burden Hours	2,000	1,500	1,500	1,794	200	6,250
Cost Per Hour to Respondent	$20	$20	$20	$20	$20	$20
Annual Cost	$40,000	$30,000	$30,000	$35,880	$4,000	$125,000

[1] In minutes.

We estimate 41,289 responses per year and an annual information collection burden of 13,244 hours.

BLM will summarize all responses to this notice and include them in the request for OMB approval. All comments will become a matter of public record.

Dated: November 18, 2004.

Ian Senio,

Bureau of Land Management, Information Collection Clearance Officer.

[FR Doc. 04–25998 Filed 11–23–04; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–310–0777–XG]

Notice of Public Meeting: Northeast California Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 (FLPMA), and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Northeast California Resource Advisory Council will meet as indicated below.

DATES: The meeting will be held Thursday and Friday, Jan. 13 and 14, 2005, in the Conference Room of the BLM Surprise Field Office, 602 Cressler St., Cedarville, California. On Jan. 13, the meeting runs from 1 to 5 p.m.; on Jan. 14, the session runs from 8 a.m. to noon. Time for public comment has been set aside for 4 p.m., Thursday, Jan. 13.

FOR FURTHER INFORMATION CONTACT: Tim Burke, BLM Alturas Field Office Manager, (530) 233–4666; or BLM Public Affairs Officer Joseph J. Fontana, (530) 252–5332.

SUPPLEMENTARY INFORMATION: The 15-member council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Northeast California and the northwest corner of Nevada. At this meeting, agenda topics will include land use planning for the Alturas, Eagle Lake and Surprise Field offices, an update on the Sagebrush-Steppe ecosystem improvement project, an update on sage grouse conservation planning, Stewardship Contracting, establishment of juniper fuelwood cutting areas, a prescribed fire update, and an update from the Black Rock-High Rock subcommittee. All meetings are open to the public. Members of the public may present written comments to the council. Each formal council meeting will have time allocated for public comments. Depending on the number of persons wishing to speak, and the time available, the time for individual comments may be limited. Members of the public are welcome on field tours, but they must provide their own transportation and lunch. Individuals who plan to attend and need special assistance, such as sign language interpretation and other

reasonable accommodations, should contact the BLM as provided above.

Dated: November 17, 2004.

Joseph J. Fontana,

Public Affairs Officer.

[FR Doc. 04–25989 Filed 11–23–04; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–926–05–9820–BJ–MT01]

Montana: Filing of Plat of Survey

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of filing of plat of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, (30) days from the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Steve Toth, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, P.O. Box 36800, Billings, Montana 59107–6800, telephone (406) 896–5121 or (406) 896–5009.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the U.S. Forest Service and was necessary to determine unsurveyed Forest Service lands. The lands we surveyed are:

Principal Meridian, Montana

T. 6 N., R. 16 W.

The plat, in six sheets, representing the dependent resurvey of a portion of certain mineral surveys, the survey of a portion of the subdivisional lines and the subdivision of sections 17 and 22, in Township 6 North, Range 16 West, Principal Meridian, Montana, was accepted November 16, 2004.

We will place copies of the plat, in six sheets, and related field notes we described in the open files. They will be available to the public as a matter of information.

If BLM receives a protest against this survey, as shown on this plat, in six sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file this plat, in six sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Dated: November 17, 2004.

Thomas M. Deiling,

Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 04–26026 Filed 11–23–04; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

National Park Service

30-Day Notice of Intention to Request Clearance of Collection of Information; Opportunity for Public Comment

AGENCY: National Park Service.

ACTION: Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995 and 5 CFR Part 1320, Reporting and Record Keeping Requirements, the NPS invites comments on a submitted request to the Office of Management and Budget (OMB) to approve an extension of a currently approved information collection (OMB No. 1024–0037). The NPS specifically requests comments on (1) The need for the information including whether the information has practical utility; (2) the accuracy of the reporting burden estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

The NPS requests comments on an application form that Federal agencies use to issue permits to qualified individuals and institutions desiring to excavate or remove archeological resources from public or Indian lands. Copies of the request and related forms and explanatory material may be obtained by contacting the individual named below.

DATES: Public comments will be accepted on or before December 27, 2004.

ADDRESSES: You may submit comments directly to the Desk Officer for the Department of the Interior (1024–0037), Office of Information and Regulatory Affairs, OMB, by fax at 202/394–6566, or by electronic mail at *oira_docket@omb.eop.gov*. Submit copies of your comments to Dr. Francis P. McManamon, Manager, Archeology and Ethnography Program, National Park Service, 1849 C Street NW. (2275), Washington, DC 20240. Street address: 1201 I Street NW. (2275), Washington, DC, 20005, Phone 202/354–2123. Fax: 202/371–5102.

If you wish to comment, you may submit your comments using several methods. You may mail comments to the postal address given here. You may fax your comments to the fax number given. You may also hand-deliver comments to the street address given here. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

To Request Printed Copies of the Documents Contact: Dr. Francis P. McManamon, Manager, Archeology and Ethnography Program, National Park Service. Mailing address: 1849 C Street NW. (2275), Washington, DC 20240. Street address: 1201 I Street, NW. (2275), Washington, DC, 20005, Phone 202/354–2123. Fax: 202/371–5102.

SUPPLEMENTARY INFORMATION:

Title: Application For and Issuance of Federal Permits Under the Archaeological Resources Protection Act and the Antiquities Act.

Departmental Form Numbers: DI–1926 (permit application), DI–1991 (permit form).

OMB Number: 1024–0037.

Expiration date: 11/30/04

Type of request: Extension of currently approved collection.

Description of need: Information collected responds to statutory requirements that Federal agencies (1) issue permits to qualified individuals and institutions desiring to excavate or remove archeological resources from public or Indian lands, and (2) specify terms and conditions, including reporting requirements, in permits. The information collected is reported annually to Congress and is used for land management purposes.

Description of respondents: Individuals, businesses, academic institutions, tribes or tribal members, Federal agencies and other parties wishing to excavate or remove archeological resources from public or Indian lands.

Estimated average number of respondents: 700.

Estimated average burden hours per response: 2.5 hours.

Estimated annual reporting burden: 1750.

Dated: October 20, 2004.

Leonard E. Stowe,

Acting NPS, Information Collection Clearance Officer, Washington Administrative Program Center.

[FR Doc. 04–26003 Filed 11–23–04; 8:45 am]

BILLING CODE 4312–52–M

DEPARTMENT OF THE INTERIOR

National Park Service

Plan of Operations, Environmental Assessment, and Draft Floodplains and Wetlands Statements of Findings, Big Thicket National Preserve, TX

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of availability of a Plan of Operations, Environmental Assessment, and draft Floodplain and Wetland Statements of Findings for a 30-day public review at Big Thicket National Preserve.

SUMMARY: Notice is hereby given in accordance with § 9.52(b) of Title 36 of the Code of Federal Regulations, Part 9, Subpart B, that the National Park Service (NPS) has received from Sanchez Oil and Gas Corporation a Plan of Operations for drilling and production of the WM Rice #1 Well from a surface location north of County Road 4825 within Big Thicket National Preserve, Tyler County, Texas. Additionally, the NPS has prepared an Environmental Assessment and draft Floodplain and Wetland Statements of Findings on this proposal.

DATES: The above documents are available for public review and comment through December 27, 2004.

ADDRESSES: The Plan of Operations, Environmental Assessment, and draft Floodplain and Wetland Statements of Findings are available for public review and comment in the Office of the Superintendent, Art Hutchinson, Big Thicket National Preserve, 3785 Milam Street, Beaumont, Texas. Copies of the Plan of Operations are available, for a duplication fee; and copies of the Environmental Assessment and draft Floodplain and Wetland Statements of Findings are available upon request, and at no cost, from the Superintendent, Art Hutchinson, Big Thicket National Preserve, 3785 Milam Street, Beaumont, Texas 77701.

FOR FURTHER INFORMATION CONTACT: Mr. Dusty Pate, Range Technician, Big Thicket National Preserve, 3785 Milam Street, Beaumont, Texas 77701, Telephone: 409 839–2689 ext. 232, e-mail at *Haigler_Pate@nps.gov.*

SUPPLEMENTARY INFORMATION: If you wish to submit comments on these documents within the 30 days; mail them to the street address provided above, hand-deliver them to the park at the street address provided above, or electronically file them to the e-mail address provided above. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: October 27, 2004.

John T. Crowley,

Acting Director, Intermountain Region, National Park Service.

[FR Doc. 04–26004 Filed 11–23–04; 8:45 am]

BILLING CODE 4312–CB–P

DEPARTMENT OF THE INTERIOR

National Park Service

Flight 93 National Memorial Advisory Commission

ACTION: Meeting notice.

SUMMARY: This notice announces a December 3, 2004, ''interim'' meeting of the Flight 93 Advisory Commission.

DATES: The public meeting will be held on December 3, 2004, from 10 to 11 a.m., eastern standard time.

Location: The meeting will be held via conference call for all out-of-town Commissioners and public participants. To call in, the call in number is 866–556–6304; then enter the pass code number 487846#. For those who are able to attend in person, the Flight 93 National Memorial office will be open at 109 West Main Street, Newberry Building, Somerset, PA 15501, from where the conference call will be initiated.

Agenda: The agenda includes:

(1) Opening of the meeting.

(2) Roll call and identification of people in the Somerset Office and on the conference call line.

(3) Report by the Design Oversight Committee of the Flight 93 Memorial Task Force, with recommendations on a Stage 1 jury for the design competition for a permanent memorial.

FOR FURTHER INFORMATION CONTACT: Joanne M. Hanley, Superintendent, Flight 93 National Memorial, 109 West Main Street, Somerset, PA 15501, telephone (814) 443–4457.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning agenda items. The statement should be addressed to the Flight 93 Advisory Commission, 109 West Main Street, Somerset, PA 15501.

This notice is being published less than 15 days prior to the meeting date because of the urgent need to complete time-sensitive work carried over from the Commission's previous meeting. In particular, the Commission must complete its consideration of Stage 1 jury recommendations by the Design Oversight Committee.

Dated: November 12, 2004.

Bernard Fagan,

Deputy Chief, National Park Service Office of Policy.

[FR Doc. 04–26002 Filed 11–23–04; 8:45 am]

BILLING CODE 4312–52–M

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Prohibited Transaction Exemption (PTE) 2004–19; Exemption Application No. D–11220]

ARINC Incorporated Retirement Income Plan (the Plan) Located in Annapolis, MD

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Grant of individual exemption.

SUMMARY: This document contains a final exemption issued by the Department of Labor (the Department) from certain prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and from certain taxes imposed by the Internal Revenue Code of 1986 (the Code). The exemption permits: (1) The in-kind contribution of the property described as the 27.5 acre headquarters

of ARINC Incorporated (ARINC or the Applicant) situated in Annapolis, MD or the ownership interests of a special purpose entity (SPE) whose only asset is this property (collectively, the Property) to the Plan by ARINC, the plan sponsor and a party in interest with respect to the Plan (the Contribution); (2) the holding of the Property by the Plan; (3) the leaseback of the Property by the Plan to ARINC (the Lease or Leaseback); (4) the repurchase of the Property by ARINC (the Repurchase) pursuant to (a) a right of first offer to ARINC should the Plan wish to sell the Property to a third party or (b) a voluntary agreement under which the Plan agrees to sell the Property to ARINC at any time during the Lease; and (5) any payments to the Plan by ARINC made pursuant to a make whole obligation as specified below (the Make Whole Payment or Obligation) (collectively, the Exemption Transactions). The exemption affects participants and beneficiaries of, and fiduciaries with respect to, the Plan.

DATES: This exemption is effective on or after November 24, 2004.

FOR FURTHER INFORMATION CONTACT: Wendy M. McColough of the Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor, telephone (202) 693–8540. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On September 13, 2004, the Department published a notice in the **Federal Register** (69 FR 55179) of a proposed individual exemption (the Proposed Exemption). The Proposed Exemption was requested in an application filed on behalf of ARINC pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 214 (2000 ed.) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Accordingly, this final exemption is issued solely by the Department.

The notice set forth a summary of the facts and representations contained in ARINC's application for exemptive relief (Application) and referred interested persons to the Application for a complete statement of the facts and representations. The Application has been available for public inspection at the Department in Washington, DC.

The notice also invited interested persons to submit comments on the Proposed Exemption and/or to request that a public hearing be held. In response to the solicitation of comments from interested persons, the Department received: Comments from ARINC; comments from Independent Fiduciary Services, Inc (IFS), the Independent Fiduciary retained to represent the Plan in connection with the exemption request; and comments from two other interested persons. None of the comments requested that a public hearing be held on the Proposed Exemption. The ARINC and IFS comments provided further information on the Exemption Transactions and are discussed below.

One comment was received from the Secretary-Treasurer of Teamsters Local 986 (Teamsters). The Teamsters represent 70 ARINC employees who participate in the Plan. The Teamsters' comment supports the Proposed Exemption, the protective conditions imposed on the Contribution by the Department, and finalizing the exemption as proposed. The other comment expressed concern about the rental rate of the Lease described in the Proposed Exemption. This concern was addressed in a response from ARINC that is summarized below.

Additionally, the following updated versions of documents discussed in the Proposed Exemption were submitted to the Department by ARINC and IFS subsequent to the publication of the Proposed Exemption in the **Federal Register**. The final transfer agreement that governs the terms upon which the Property will be contributed to and held by the Plan and is between ARINC (the Transferor), Aeronautical Radio, Inc. (ARI), a wholly-owned subsidiary of ARINC, and the Plan through its agent, IFS, executed on October 12, 2004 (the Transfer Agreement), was received by the Department on October 19, 2004. On November 5, 2004, the Department received the November 4, 2004 second addendum to the December 8, 2004 letter agreement between IFS, ARINC, and the Pension Committee of the Plan concerning the engagement of IFS as the Independent Fiduciary, as amended July 30, 2004 (the IF Agreement).

The final lease that governs the terms upon which the Property will be leased back to ARINC by the Plan (Lease) was received by the Department on November 15, 2004. In correspondence, dated November 11 and November 15, 2004, ARINC submitted the Lease and stated that the Lease is consistent with the material terms and conditions of the lease term sheet, as revised on June 11, 2004 (Lease Term Sheet). By letter dated November 15, 2004, ARINC provided additional information to the Department summarizing the provisions in the Lease that supplement the provisions of the Lease Term Sheet described in the Proposed Exemption.

The Lease is an agreement by and between ARINC as Tenant and 2551 Riva Road, Inc., an SPE. ARINC states that under the Lease, 2551 Riva Road, Inc., a Delaware corporation, will be the Landlord. This corporation is initially being established as a subsidiary of ARI, which currently holds title to the Property. ARI will transfer title to the Property to 2551 Riva Road, Inc. on or before the date of closing when the proposed Contribution and Leaseback transactions are consummated in accordance with the Transfer Agreement (the Closing). On the date of Closing, ARI will convey all of the stock of 2551 Riva Road, Inc. to the Plan so that the Landlord will be a wholly owned subsidiary of the Plan. The Certificate of Incorporation of 2551 Riva Road, Inc. was filed in the State of Delaware on November 15, 2004. The initial officers and directors are ARINC employees. ARINC expects that new officers and directors will be appointed by IFS on behalf of the Plan the day of or the day after Closing.

ARINC notes that the Department described certain provisions of the Lease Term Sheet at Paragraph 6 of the Summary of Facts and Representations in the Proposed Exemption at column 3 of 69 FR 55181. ARINC represents that these descriptions in the Proposed Exemption generally remain accurate. However, as applicable, ARINC provides the following additional information based on modifications to the terms and conditions of the Lease Term Sheet as agreed to in the Lease.

Bondable/Triple Net Lease Structure

As noted in the ARINC comment below, during the bondable period, the Lease Term Sheet and the Lease provide for an abatement of rent in the event of a partial condemnation at article 14.4(b) of the Lease and the right to terminate the Lease under certain circumstances in the condemnation and casualty contexts (Lease, arts. 13 and 14).

The Lease Term Sheet provides that there shall be a commercially reasonable standard for determining whether capital improvements (or repair or replacement) are required for the Property during the bondable period. The Lease provides the commercially reasonable standard by requiring the preparation of a reasonable annual budget to be approved by Landlord and Tenant for items needing repair, maintenance or replacement over the coming year (Lease, art. 8.1), based on an annual inspection by a reputable building inspector and an agreed

standard of keeping the buildings in good condition and repair, in a manner befitting that of comparable buildings in the Annapolis, Maryland area and in accordance with all applicable laws and the Lease (Lease, art. 8.2). Disagreements regarding the timing or scope of any repair, maintenance or replacement, if any, are resolved in accordance with a neutral third-party arbitration process that is binding on the parties (Lease, art. 23.4).

Rental Rate

The Lease provides for base rent of $4,290,189 during the first year of the Lease (Lease, art. 1.5), increased by 2.5% annually (Lease, art. 4.2), with an increase to $6,488,302 for the first year of the non-bondable period (Lease, art. 4.1), increased by 2.5% annually (Lease, art. 4.2). ARINC notes that these figures are consistent with those described in the Proposed Exemption.

The terms of the Exemption Transactions, however, require an updated appraisal prior to Closing, and ARINC states that the rental amounts may be modified based on such updated appraisal. ARINC believes that a substantial change in the rent is not expected.

The Right of First Offer (ROFO)

ARINC states that article 21 of the Lease provides an additional right for the Landlord in the event the ROFO is triggered from or after the 15th anniversary of the Lease commencement date (the date of Closing under the Transfer Agreement) and a three-appraiser method is used for the determination of fair market value for the Property. In this situation, the Landlord has the right, exercisable within 10 days following the appraisers' determination, to withdraw its notice of transfer and continue to hold the Property (Lease, art. 21.2).

The Lease includes a provision whereby if the Tenant elects to purchase under the ROFO, the parties are to enter into a purchase and sale agreement that incorporates the terms of the right of first offer but is otherwise in substantially the same form as the Transfer Agreement for the initial transfer of the Property to Landlord, except that (i) no additional appraisal is required (inapplicable, since it is not necessary to set any rent), (ii) only a subset of the representations and warranties provided to the Landlord upon the initial transfer shall be required to be provided to the Tenant/purchaser (Exhibit F of the Lease), and (iii) Tenant/purchaser will not be entitled to any study period as long as title to the Property has not changed in any manner other than as previously approved by Tenant (Lease, art. 21.4).

ARINC provides that in article 21.6 of the Lease, the ROFO terms have been clarified so that it is not applicable with respect to easements and the like, as well as to any (i) transfer to an affiliate of the Landlord, (ii) transfer to Landlord's lender (or a third party) as a result of a foreclosure or deed in lieu of foreclosure, or (iii) transfer to a third party in a condemnation proceeding, however, in the event of a transfer described in clause (i), the ROFO shall apply to the first transfer by the affiliate of the Landlord, and in the event of a transfer described in clause (ii), the ROFO shall apply to the first transfer by the lender/third party. The Tenant loses its rights altogether in the event of a transfer described in clause (iii).

Article 21 of the Lease adds a provision whereby if the purchase price of the unsolicited offer that Tenant elects to match is to be paid by other than cash, the Tenant will be required to pay the fair market value of the non-cash consideration (Lease, art. 21.7).

Indemnification

ARINC represents that the Tenant's indemnification of the Landlord during the non-bondable period has been broadened in the Lease to include violations of environmental laws, the Americans with Disabilities Act and other health and/or safety laws resulting from acts or omissions of any invitee, agent, employee, affiliate, subtenant, assignee, contractor, client, family member, licensee, customer or guest of Tenant (collectively, Invitees) as opposed solely to acts or omissions of Tenant or any sublessee or assignee (Lease, art. 12.2). Additionally, article 12.6 of the Lease provides that the liability of the Landlord is limited to its interest in the Property and any sales proceeds, rents, insurance proceeds and condemnation awards related thereto.

ARINC Default

In the event of a Tenant payment default, the Proposed Exemption stated that the Lease would contain commercially reasonable provisions regarding late fees and default interest. To address this, the Lease provides for a late fee of $1,000 if the Tenant fails to make any payment within five days after due without regard to any notice and cure period otherwise provided under the Lease (Lease, art. 15.7) and default interest on such overdue payment from the date due until payment at the lesser of (i) one percentage point above the prime rate or (ii) the highest lawful rate per annum (Lease, arts. 15.6 and 15.7). Article 15.7 provides that the Landlord waives the late charge and default interest the first time in any 12-month period that Tenant fails to make a payment when due, provided the payment is made prior to the expiration of the five-business day notice and cure period.

By correspondence dated November 11, 2004, ARINC's real estate counsel provided the following Lease provisions that counsel believes expanded the protections for the Plan from that contemplated by the Lease Term Sheet.

Hazardous Materials

Article 6.3 of the Lease provides that ARINC take substantially increased liability for hazardous materials. The ARINC real estate counsel asserts that ARINC is taking virtually all liability for asbestos, tanks and transformers, whether or not caused by ARINC or its Invitees, and taking expanded liability for other hazardous materials violations not caused by ARINC.

Insurance

In article 11.1 of the Lease, ARINC has agreed to obtain a substantially larger amount of liability insurance from that specified in the Lease Term Sheet. The umbrella liability coverage has been increased from $5,000,000 to $25,000,000 in the Lease. ARINC's all-risk property insurance coverage has been increased to include $5,000,000 of ordinance or law coverage and in addition, ARINC has agreed to purchase a separate liability policy for the Plan with excess umbrella coverage of $10,000,000.

Casualty

ARINC's real estate counsel states that ARINC has agreed to a substantial additional condition to its ability to terminate the Lease in the event of a casualty during the non-bondable period as provided in article 13.2 of the Lease. If the Property is totally or partially damaged or destroyed, the remainder of the Property must be unsuitable for ARINC's business purposes for ARINC to have the right to terminate the Lease.

Reporting Requirements

In article 23.3 of the Lease, ARINC has agreed to additional ongoing reporting requirements by notifying the Landlord regarding defaults under ARINC loans that could materially adversely affect ARINC's ability to perform its obligations under the Lease.

Discussion of the Comments

IFS Comment

By letters dated October 19 and November 5, 2004, IFS provided the

following comments and additional information to the Department.

1. Diversification of the Plan's Assets Condition

IFS observes that subsection (h) of section II of the Proposed Exemption describes one of the duties of IFS as Independent Fiduciary as follows:

(h) The Independent Fiduciary determines on an ongoing basis that the amount of plan assets invested in employer real property and employer securities, including its interests in the Property, complies with ERISA;

IFS believes that its specific obligations in regard to the diversification of plan assets are set forth in the July 20, 2004 amendment and addendum to the IF Agreement, and as described at the first bullet in the second column at 69 FR 55187 of the Proposed Exemption, as follows:

In considering whether and on what terms to seek prudently to sell the Property, IFS shall consider the nature, value and other relevant aspects of the Property in isolation, as well as the nature and diversification of the Plan's overall investment portfolio. Insofar as IFS determines that continued ownership of the Property poses undue risk to the Plan of over concentration from an investment perspective, IFS shall determine and take appropriate action to seek prudently to reduce such risk.

IFS' concern is that section II(h) in the Proposed Exemption overstates IFS'' authority. IFS notes that while IFS is required to consider the other assets of the Plan, including any employer real property and employer securities, in determining whether and to what extent continued ownership of the Property may adversely affect the diversification of the Plan's overall portfolio, the IF Agreement does not give IFS any responsibility for or authority over those other assets. Section II(h), however, could be read to mean that IFS must determine on an ongoing basis whether all investments by the Plan in employer real property and employer securities, not just the Property, comply with any aspect of ERISA, not just diversification. Under that reading, IFS would be obligated to take action if, for example, the Plan has invested in employer securities that are not qualifying employer securities under ERISA section 407. IFS asserts that this goes beyond IFS'' role as contemplated by the IF Agreement, as amended.

To clarify that the objective of section II(h) is to require compliance with the fiduciary responsibility provision of ERISA, IFS proposes that the phrase ''employer real property and employer securities, including its interests in'' be deleted and that the phrase ''section 404(a)(1) of'' be inserted in section II(h), so that the provision would read as follows:

(h) The Independent Fiduciary determines on an ongoing basis that the amount of Plan assets invested in the Property complies with section 404(a)(1) of ERISA;

IFS believes that this would be sufficient to make clear that IFS is obligated to determine on an ongoing basis that the concentration of Plan assets in the Property is consistent with the ERISA fiduciary duty of diversification, without requiring IFS to make determinations as to Plan investments other than the Property.

The Department has determined that it would be appropriate to modify section II(h) as requested by IFS.

2. Make Whole Payment Condition

IFS notes that subsection (i) of section II of the Proposed Exemption describes the Make Whole Payment using language that is based on the IFS report to the Department on June 18, 2004 (the IFS Report). The two elements of the Make Whole Payment are set forth in section II(i) as follows:

The actual return component—''the combination of the proceeds from a sale of the Property (or the change in the value of the Property if the Plan continues holding it over the full five years) plus the Plan's net income on the Property under the Lease prior to the sale (or over the full five years)''

The target return component—''the Property's value as of the date of the Contribution plus a 5% compounded rate of return on that value plus the costs of holding and maintaining the Property''

If the target return component exceeds the actual return component at the time for determining the Make Whole Payment, then ARINC is obligated to contribute the difference to the Plan.

IFS explains that the description in the IFS Report was based on an early version of the Make Whole Payment provision of the Lease Term Sheet, which has since been refined. IFS states that the final version is contained in article 22 of the Lease and that the language in section II(i), while less detailed than the final provision in the Lease, is generally consistent with that provision, except in one respect: The target return component in the Lease provision does not include the costs of holding and maintaining the Property. The reason is that these costs have already been deducted from the actual return component, as reflected in the use of the term ''net income'' in the above language. The Lease provision itself refers to the rental income received by Landlord under this Lease up to the Make-Whole Date, ''less expenses incurred by Landlord with respect to the Premises and this Lease.'' To deduct the costs from the actual return, and then add them to the target return, would be to count them twice.

Accordingly, IFS requests that section II(i) be amended to delete the phrase ''plus the costs of holding and maintaining the Property'' from subparagraph (ii) in the second paragraph. To the extent the IFS Report does not accurately reflect this provision, IFS states that it hereby amends the IFS Report to be consistent with this discussion and that this change does not affect the conclusions in the IFS Report.

The Department has determined that it would be appropriate to modify section II(i) as requested by IFS.

3. Status of the Monetization

IFS comments that Paragraph 11 of the Summary of Facts and Representations in the Proposed Exemption at column 3 of 69 FR 55191, in describing the IFS Report, states the following regarding the status of proposals to monetize the lease payment stream:

IFS notes that while they continue to engage financial institutions in discussions of various proposals, they do not expect that a monetization transaction will occur.

Since the date of the IFS Report, IFS represents that it has ceased to engage financial institutions in discussions. IFS remains open to proposals to monetize the stream of lease payments, but is not actively pursuing that course at this time. IFS continues to expect that it is unlikely that a monetization transaction will occur, for the reasons described in the IFS Report.

4. Status of Due Diligence

IFS notes that, in Paragraph 5 of the Summary of Facts and Representations in the Proposed Exemption at column 3 of 69 FR 55180, under the terms of the Transfer Agreement, the Plan will have a 60-day Review Period after execution of the Transfer Agreement to undertake a review and examination of all aspects of the Property prior to closing the transaction, should IFS approve going forward with the transaction.

IFS reports that the Transfer Agreement has now been executed, effective October 12, 2004, so that the 60-day review period runs until December 11th. However, prior to the execution date, and consistent with the intent of the Transfer Agreement, ARINC and ARI made the requested Property documents available to IFS for review, and IFS' representatives and consultants were permitted to enter upon the Property to conduct specific examinations, such as structural

examinations of buildings and environmental testing. If IFS completes its due diligence to its satisfaction prior to the expiration of the 60-day Review Period, it may waive any remaining portion of the Review Period, in order to close the transaction sooner so that the Plan may begin to benefit from receipt of the rental income.

By letter dated November 5, 2004, IFS informed the Department that Custer Environmental, Inc. (Custer), retained by IFS to conduct a ''Phase One Environmental Site Assessment'' of the Property, provided a final environmental report to IFS dated October 25, 2004. On the basis of its review of the Custer report, IFS states that it is satisfied that there are no environmental issues that would cause it not to close on the acquisition of the Property and the lease to ARINC in accordance with the provisions of the Transfer Agreement and the Lease.

5. Liability Insurance

IFS notes that in addition to the expenses that may be Incurred by the special purpose entity owned by the Plan (the SPE) as the Landlord under the terms of the Lease, and by the Plan pursuant to the IF Agreement, the Plan will be incurring the expense of directors' and officers' liability insurance in connection with the ongoing operation of the SPE. This expense is presently estimated to be $18,000 per year, which may change over time in accordance with market conditions.

ARINC Comment

By letter dated October 19, 2004, the Department received the following comments from ARINC.

1. Effective Date of the Exemption

ARINC explains that, at the request of ARINC, the Proposed Exemption provides that, if granted, the final exemption will have an effective date of September 7, 2004. This effective date was requested to allow ARINC to make the Contribution prior to the grant of a final exemption. ARINC considered making the Contribution before September 15, 2004 to, among other considerations, avoid having to make a variable rate premium payment to the Pension Benefit Guaranty Corporation in the amount of $910,000. However, ARINC reports that it has subsequently decided not to Contribute the Property until after the grant of a final exemption. By doing so, ARINC avoids the possibility that a final exemption would be granted on terms different than provided for in the Proposed Exemption, which could expose ARINC to excise tax penalties under Code section 4975. As a result of ARINC's decision, the relief necessary under the exemption need be only prospective since the transaction will not occur until after a final exemption is granted. ARINC adds that the decision to delay the transaction, while made by ARINC, is supported by IFS, the Plan's Independent Fiduciary.

The Department concurs with the ARINC comment and has determined that the effective date of the exemption will be on or after the date of publication of this final exemption in the **Federal Register**.

2. The Lease Terms

ARINC notes that the Proposed Exemption was issued based on a Lease Term Sheet, which was submitted to the Department while ARINC and IFS negotiated the more detailed terms of the Lease. However, ARINC represented that the Lease Term Sheet would accurately reflect the provisions of the more detailed final Lease.

ARINC submits two clarifications regarding the description of the Lease in the Proposed Exemption. In Paragraph 6 of the Summary of Facts and Representations in the Proposed Exemption at column 1 of 69 FR 55182, under the discussion entitled ''Bondable/Triple Net Lease Structure,'' the Department states ''Under the bondable lease structure, the rent payable by ARINC to the Plan remains payable *under all circumstances* * * *.'' (emphasis added). ARINC states that this is consistent with the Lease Term Sheet, but ARINC notes that the Lease Term Sheet also provides for an abatement of rent in the event of partial condemnation (based on the portion of the property subject to condemnation) as well as a tenant right to terminate the lease under certain circumstances, such as in the event of condemnation or casualty.

Secondly, at column 2 of 69 FR 55183, under the Department's discussion entitled ''The Right of First Offer,'' ARINC and the IFS Report described the fair market value determination for the purchase price as changing for year 15 of the Lease and beyond. ARINC clarifies that this is not entirely accurate, because the Lease Term Sheet and the Lease provides for the fair market value determination to change from and after the 15th anniversary of the Lease commencement date (which would actually be year 16 and beyond). Accordingly, the two references in the Proposed Exemption at 69 FR 55183 to ''14'' should instead refer to ''15,'' and the two references to ''15'' should instead refer to ''16.''

3. Liability for Hazardous Substances

ARINC states that section II(m) of the Proposed Exemption includes a condition which provides that ''ARINC indemnifies the Plan with respect to all liability for hazardous substances released on the Property prior to the execution and closing of the Contribution of the Property.'' ARINC requests that the Department confirm ARINC's understanding that the provisions of the Transfer Agreement satisfy this condition. In particular, under section 5(a)(12) of the Transfer Agreement, ARINC has represented that to its knowledge no hazardous substances have been released on the Property as of the closing date of the Transfer Agreement. Section 5(f) of the Transfer Agreement provides an indemnity in the event that ARINC breaches this representation.

ARINC notes that in response to a request by IFS, the Plan's Independent Fiduciary, ARINC agreed to modify its representation in section 5(a)(12) of the Transfer Agreement to state that, to ARINC's knowledge, the construction and condition of certain rooms in buildings on the Property that were not accessible to Custer Environmental, Inc. (IFS's environmental consultant), are the same in all material respects as other rooms in the same buildings that were inspected by Custer, and that the inaccessible rooms do not have any Hazardous Substances in violation of Environmental Laws. This change is an improvement from the Plan's perspective and provides greater assurance to IFS and the Plan of the condition of the Property. As stated previously, on the basis of IFS's review of the Custer report, IFS is satisfied that there are no environmental issues that would cause it not to close on the Exemption Transactions.

The Department confirms that the provisions of the Transfer Agreement and the Lease, IFS's due diligence regarding the Property as stated in the IFS Report, and IFS's approval of the Custer Environmental Site Assessment (as described above) appears to satisfy the condition of section II(m) of the Proposed Exemption.

4. The Make Whole Payment Condition

ARINC represents that the Make Whole Payment condition provided under the Proposed Exemption is consistent with the agreement of ARINC and IFS in the Lease Term Sheet and the Lease. ARINC notes, however, that both the Lease Term Sheet and the Lease provide ARINC 180 days from the date that is the earlier of the date of sale of the Property by the Plan or five years

from the closing of the transaction to make the Make Whole Payment. However, the 180-day period is not specifically reflected in the language of the Make Whole Payment condition in section II(i) of the Proposed Exemption. ARINC ask that the Department confirm ARINC's understanding that, consistent with the Lease Term Sheet, the Lease, and the Summary of Facts and Representations in the Proposed Exemption at column 2 of 69 FR 55183, ARINC will have 180 days to make a Make Whole Payment if any such payment is required.

The Department confirms that the Lease Term Sheet, the Lease, and the language of the Proposed Exemption provide that ARINC will have 180 days to make the Make Whole Payment.

5. Diversification of the Plan Assets Condition

ARINC states that subsection (h) of section II of the Proposed Exemption includes a condition that requires that the ''Independent Fiduciary determines on an ongoing basis that the amount of plan assets invested in employer real property and employer securities, including its interest in the Property, complies with ERISA.'' ARINC notes that ARINC's engagement of IFS grants IFS the discretion to determine whether the holding of the Property satisfies ERISA's fiduciary requirements, and the engagement letter requires that IFS evaluate the nature and diversification of the Plan's overall investment portfolio in making this judgment. However, IFS has not been appointed Independent Fiduciary of the Plan to make decisions with respect to real property or securities other than the Property. As such, ARINC believes that this condition should be narrowed somewhat. ARINC understands that IFS concurs with this comment, and has filed its own letter requesting that this condition be narrowed. ARINC supports their request.

6. Plan Contributions Update

ARINC confirms that it made $18 million in contributions for the 2003 Plan Year. In addition, ARINC still expects to fully fund the Plan to the ABO level after all cash contributions and the Property contribution are made for the 2004 Plan Year (subject to any unexpected declines in the market value of assets or further declines in interest rates). To date, ARINC represents that it has already contributed $6 million for the 2004 Plan Year, which exceeds the minimum required contribution of $2.224 million for the Plan Year.

By letter to the Department, dated November 2, 2004, ARINC further updated its contribution information and stated that on October 29, 2004, ARINC contributed an additional $2 million to the Plan for a cumulative total contribution of $8 million thus far for the 2004 plan year. ARINC noted that these contributions far exceed the minimum required contribution of $2.24 million for the 2004 Plan Year.

Rental Rate Comment

By letter to the Department, dated October 8, 2004, one commenter objected to the annual base rent of $12.40 per square foot under the bondable structure at column 2 of 69 FR 55182.

The commenter stated that the independent appraiser, Deloitte & Touche LLP (Deloitte), recommended that the initial rate for the bondable period be set at a higher rate of $13.35 per square foot, and provided the opinion that ''[t]here is no justification for ARINC to not pay the full amount recommended by the independent appraiser.''

By letter to the Department, dated November 2, 2004, ARINC responded to the October 8, 2004 comment. ARINC explained that the $13.35 initial rent for the bondable period was set forth in the Deloitte draft report dated May 25, 2004. That appraisal set an overall property value of the ARINC headquarters Property at $52 million. The final report by Deloitte, dated June 17, 2004, reduced the overall Property value to $49 million. The reductions were made in response to specific concerns raised by IFS that the $52 million valuation was too high as described in the Proposed Exemption at 69 FR 55189 to 55190. ARINC states that when Deloitte reduced the Property's appraised value, it also reduced the rental rate. For the bondable period, the reduction was from $13.35 per square foot to $12.40 per square foot. ARINC notes that this change in lease rates is discussed in the Proposed Exemption in the first column at 69 FR 55190. The summary table that appears on the same page did not include the changed lease rates. ARINC emphasizes that the IFS Report concludes that the $49 million property valuation, and the corresponding $12.40 per square foot rental rate, are appropriate and the transaction is in the interest of the Plan.

Determination of the Department

Accordingly, based upon the representations made by the Applicant, the additional documents submitted to the Department, the written comments received in response to the Proposed Exemption, and the analysis conducted by the Independent Fiduciary, the Department has determined to grant the exemption subject to the modifications discussed above. The Department has, in transactions of this nature, placed emphasis on the need for an Independent Fiduciary and on such Independent Fiduciary's considered and objective evaluation of the transactions. In its deliberations, which included its analysis of all aspects of the transactions, the Independent Fiduciary has consistently represented for the record that no transactions concerning the Property will be accepted on behalf of the Plan unless such transactions are found by the Independent Fiduciary to be in the interests of the Plan. Finally, the Department notes that the Independent Fiduciary's satisfaction of its obligations in connection with the determination of the fair market value of the Property, the ongoing determination that the amount of Plan assets invested in the Property complies with section 404(a)(1) of ERISA as described above, and other obligations as previously described by the Department in the Summary of Facts and Representations in the Proposed Exemption is a critical factor in the Department's decision to grant a final exemption.

The Application pertaining to the exemption, the Proposed Exemption, the comments submitted to the Department and the responses to the comments, and all other documents submitted to the Department concerning this exemption have been included as part of the public record of the Application. The complete Application file, including all supplemental submissions received by the Department, is available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue, NW., Washington, DC 20210.

For a complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the September 13, 2004 Notice of Proposed Exemption at 69 FR 55179.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act,

which require, among other things, that a fiduciary discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirements of section 401(a) of the Code that the plan operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The exemption will not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code;

(3) In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department finds that the exemption is administratively feasible, in the interests of the plans and their participants and beneficiaries and protective of the rights of the participants and beneficiaries of the plans;

(4) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(5) The availability of this exemption is subject to the express condition that the material facts and representations contained in the Application are true and complete and accurately describe all material terms of the transactions that are the subjects of the exemption.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department finds that the exemption is:

(a) Administratively feasible;

(b) In the interests of the Plan and its participants and beneficiaries; and

(c) Protective of the rights of the participants and beneficiaries of the Plan.

Section I. Covered Transactions

The restrictions of sections 406(a), 406(b)(1) and (b)(2), and 407(a) of the Act, and the sanctions resulting from the application of section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to:

(a) the transfer of the property described as the 27.5 acre headquarters of ARINC Incorporated (ARINC) situated in Annapolis, MD or the ownership interests of a special purpose entity (SPE) whose sole asset is this property (collectively, the Property) to the Plan through the in-kind contribution of such Property by ARINC, the plan sponsor and a party in interest with respect to the Plan (the Contribution);

(b) the holding of the Property by the Plan;

(c) the leaseback of the Property by the Plan to ARINC (the Lease or Leaseback);

(d) the repurchase of the Property, by ARINC (the Repurchase) pursuant to (1) a right of first offer as specified in the Lease should the Plan wish to sell the Property to a third party or (2) a voluntary agreement under which the Plan agrees to sell the Property to ARINC at any time during the Lease; and

(e) any payments to the Plan by ARINC made pursuant to the make whole obligation as specified in the Lease (Make Whole Payment) (collectively, the Exemption Transactions).

Section II. Conditions

This exemption is conditioned upon adherence to the material facts and representations described herein and upon satisfaction of the following requirements:

(a) A qualified independent fiduciary (the Independent Fiduciary) acting on behalf of the Plan, represents the Plan's interests for all purposes with respect to the Contribution and determines, prior to entering into any of the Exemption Transactions described herein, that each such transaction is in the interests of the Plan;

(b) The Independent Fiduciary negotiates and approves the terms of any of the transactions between the Plan and ARINC that relate to the Property;

(c) The Independent Fiduciary manages the holding, leasing, and disposition of the Property and takes whatever actions it deems necessary to protect the rights of the Plan with respect to the Property;

(d) The terms and conditions of any transactions between the Plan and ARINC concerning the Property are no less favorable to the Plan than terms negotiated at arm's length under similar circumstances between unrelated third parties;

(e) The contribution value of the Property is the fair market value of the Property as determined by the Independent Fiduciary on the date the Property is contributed to the Plan. In determining the fair market value of the Property, the Independent Fiduciary obtains an updated appraisal from a qualified, independent appraiser selected by the Independent Fiduciary, and ensures that the appraisal is consistent with sound principles of valuation;

(f) The Lease has an initial term of twenty years, with a three-year renewal term. The Lease is a bondable lease for the first ten years of the Lease (or such earlier date specified in the Lease as agreed to between the Lessor and ARINC). During the bondable period ARINC, as lessee, pays, in addition to the base rent, all costs associated with the Property, including capital expenditures. After the bondable period expires, the Lease shall convert to a traditional triple net lease under which ARINC, as lessee, pays, in addition to the base rent, all normal operating expenses of the Property, including taxes, insurance, maintenance, repairs, and utilities, but does not pay capital expenditures;

(g) The Independent Fiduciary has sole authority to determine if it is in the interest of the Plan to enter into a transaction to sell the stream of lease income on the Property to a third party for cash (the Monetization);

(h) The Independent Fiduciary determines on an ongoing basis that the amount of Plan assets invested in the Property complies with section 404(a)(1) of ERISA;

(i) At the earlier of: (i) The date the Plan sells the Property for fair market value or (ii) the date five years from the date of the Contribution, ARINC will transfer to the Plan a Make Whole Payment, as described below, in order to guarantee the Plan a minimum rate of return of 5% compounded per annum on the initial contributed value of the Property; provided that, if a Make Whole Payment is due and if, for the taxable year of ARINC in which the Make Whole Payment is to be made, such Make Whole Payment (i) would not be deductible under section 404(a)(1) of the Code or (ii) would result in the imposition of an excise tax under section 4972 of the Code, such Make Whole Payment would not be made until the next taxable year of ARINC for which the Make Whole Payment is deductible under section 404(a)(1) of the Code and does not result in an excise tax under section 4972 of the Code;

ARINC will guarantee a minimum return of 5% to the Plan by agreeing that if (i) the combination of the proceeds from a sale of the Property (or the change in the value of the Property if the Plan continues holding it over the full five years) plus the Plan's net

income on the Property under the Lease prior to the sale (or over the full five years) is less than (ii) the Property's value as of the date of the Contribution plus a 5% compounded rate of return on that value, then (iii) ARINC will contribute to the Plan the difference necessary to provide the 5% return. The calculation of the Make Whole Payment will take into account the status of any Monetization of the lease payments as of the time of sale or five-year anniversary of the Contribution.

(j) If the Plan desires to sell or convey the Property or its interest therein during the Lease Term, the Plan must first offer ARINC the right to purchase or otherwise acquire the Property or such interest therein on such terms and conditions as the Plan proposes to market the Property or such interest therein for sale (the Right of First Offer). If ARINC fails to exercise such right to purchase, the Plan generally is free to sell the Property to a third party. The right of first offer shall terminate upon the commencement of the exercise by the Plan of its remedies under the Lease as the result of a monetary event of default by ARINC as described in the Lease that continues uncured following notice and the expiration of applicable cure periods (and a second notice and cure period provided fifteen (15) days before the loss of such right on account of such default);

(k) The Plan pays no commissions or fees in connection with the Contribution, the Lease, the Repurchase, or the Monetization of the Property. This condition does not preclude the Plan from paying the ongoing costs associated with the holding of the Property that are not the responsibility of ARINC under the Lease;

(l) Subject to ARINC's Right of First Offer, the Plan retains the right to sell or assign, in whole or in part, any of its Property interests to any third party purchaser; and

(m) ARINC indemnifies the Plan with respect to all liability for hazardous substances released on the Property prior to the execution and closing of the Contribution of the Property.

Section III. Definitions

(a) The term ''Independent Fiduciary'' means a fiduciary who is:

(1) independent of and unrelated to ARINC or its affiliates, and

(2) appointed to act on behalf of the Plan for all purposes related to, but not limited to (i) the in-kind contribution of the Property by ARINC to the Plan, and (ii) other transactions between the Plan and ARINC related to the Property.

For purposes of this exemption, a fiduciary will not be deemed to be independent of and unrelated to ARINC if:

(1) such fiduciary directly or indirectly controls, is controlled by or is under common control with ARINC,

(2) such fiduciary directly or indirectly receives any compensation or other consideration in connection with any transaction described in this exemption; except that an Independent Fiduciary may receive compensation for acting as an Independent Fiduciary from ARINC in connection with the transactions contemplated herein if the amount or payment of such compensation is not contingent upon or in any way affected by the Independent Fiduciary's ultimate decision, and

(3) the annual gross revenue received by such fiduciary, during any year of its engagement, from ARINC and its affiliates exceeds 5 percent (5%) of the fiduciary's annual gross revenue from all sources for its prior tax year.

(b) The term ''affiliate'' means:

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee, relative, or partner of any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(c) The term ''control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

Signed at Washington, DC, this 19th day of November 2004.

Ivan L. Strasfeld,

Director, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 04–26067 Filed 11–23–04; 8:45 am]

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DEPARTMENT OF LABOR

Emergency Benefits Security Administration

[Prohibited Transaction Exemption 2004–20; Exemption Application No. D–11098, et al.]

Grant of Individual Exemption; Comerica Bank

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

A notice was published in the **Federal Register** of the pendency before the Department of a proposal to grant such exemption. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, DC. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicant has represented that it has complied with the requirements of the notification to interested persons. No requests for a hearing were received by the Department. Public comments were received by the Department as described in the granted exemption.

The notice of proposed exemption was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 4089a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemption is administratively feasible;

(b) The exemption is in the interests of the plan and its participants and beneficiaries; and

(c) The exemption is protective of the rights of the participants and beneficiaries of the plan.

Comerica Bank
Located in Detroit, Michigan
[Prohibited Transaction Exemption 2004–20;
Exemption Application No. D–11098]

Exemption

Section I. Exemption for Receipt of Fees

The restrictions of sections 406(a) and 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section

4975(c)(1)(A) through (F) of the Code, shall not apply to the receipt of fees by Comerica Bank and its affiliates (Comerica) from the Munder Funds (the Funds), open-end investment companies registered under the Investment Company Act of 1940 (the 1940 Act), for acting as an investment adviser for the Funds which are not investment advisory services (''Secondary Services'' as defined in Section III(h) below) in connection with the purchase and sale of shares of the Funds by certain defined benefit and defined contribution pension plans and funded employee welfare benefit plans (Client Plans) for which Comerica serves as fiduciary with investment discretion, provided that the following conditions and the General Conditions set forth in Section II are met:

(a) No sales commissions, redemption fees, or other fees are paid by the Client Plans in connection with the purchase or sale of shares of the Funds.

(b) The price paid or received by a Client Plan for shares in a Fund is the net asset value per share, as defined in Section III(e), at the time of the transaction, and is the same price that would have been paid or received for the shares by any other investor at that time.

(c) Comercia, including any officer or director of Comerica, does not purchase or sell shares of the Funds from or to any Client Plan.

(d) Each Client Plan receives a credit, through a cash rebate of such Plan's proportionate share of all fees charged to the Funds by Comerica for investment advisory services, including any investment advisory fees paid by Comerica to third-party subadvisers. Cash rebates for investment advisory services provided to the Client Funds are received by a Plan on or before the date Comerica charges the Client Plan for plan-level investment management services. Comerica management fees and Munder advisory fees are paid in arrears for services provided to the Client Plans and the Funds, respectively. The crediting of all such fees is audited by Comerica through a system of internal controls to verify the proper crediting of the fees to each Client Plan.

(e) Comerica will supply, annually and upon request, to the second fiduciary acting for a Client Plan, who is independent of and unrelated to Comerica (the Second Fiduciary), all information reasonably necessary for such fiduciary to verify that the fee credit calculation is correct and any additional information that the Second Fiduciary may require to determine that the conditions of this exemption are being met by Comerica.

(f) For each Client Plan, the combined total of all fees received by Comerica for the provision of services to a Client Plan, and in connection with the provisions of services to the Funds in which the Client Plan may invest, is not in excess of ''reasonable compensation'' within the meaning of section 408(b)(2) of ERISA.

(g) Comerica does not receive any fees payable pursuant to Rule 12b–1 under the 1940 Act in connection with the transactions.

(h) The Client Plans are not employee benefit plans sponsored or maintained by Comerica.

(i) The Second Fiduciary receives, in advance of any initial investment by the Client Plan in a Fund, full and detailed written disclosure of information concerning the Fund, including, but not limited to:

(1) A current prospectus for each Fund in which a Client Plan is considering investing;

(2) A statement describing the fees for investment advisory or similar services and any Secondary Services as defined in Section III(h), and all other fees to be charged to or paid by the Client Plan and by the Funds, including the nature and extent of any differential between the rates of such fees;

(3) The reasons why Comerica may consider such investment to be appropriate for the Client Plan; A statement describing whether there are any limitations applicable to Comerica with respect to which assets of a Client Plan may be invested in the Funds, and if so, the nature of such limitations; and upon the request of the Second Fiduciary, a copy of the proposed exemption and/or a copy of the final exemption once such documents are published in the **Federal Register**.

(j) After consideration of the information described in paragraph (i) above, the Second Fiduciary authorizes in writing the investment of assets of the Client Plan in each particular Fund, the fees to be paid by such Fund to Comerica, and the cash rebate to the Client Plan of fees received by Comerica from the Funds for investment advisory services.

(k) All authorizations made by a Second Fiduciary regarding investments in a Fund and the fees paid to Comerica are subject to an annual reauthorization wherein any such prior authorization referred to in paragraph (j) above shall be terminable at will by the Client Plan, without penalty to the Plan, upon receipt by Comerica of written notice of termination. A form expressly providing an election to terminate the authorization described in paragraph (j) above (the Termination Form) with instructions on the use of the form must be supplied to the Second Fiduciary no less than annually. However, if the Termination Form has been provided to the Second Fiduciary pursuant to paragraph (m) below, then the Termination Form need not be provided again for an annual reauthorization pursuant to this paragraph unless at least six months have elapsed since the form was provided in connection with the additional service or fee increase. The instructions for the Termination Form must include the following information:

(1) The authorization is terminable at will by any of the Client Plans, without penalty to such Client Plans, upon receipt by Comerica of written notice from the Second Fiduciary; and

(2) Failure by the Second Fiduciary to return the Termination Form on behalf of a Client Plan will result in continued authorization of Comerica to engage in the transactions described in paragraph (j) above on behalf of the Client Plan.

(3) A copy of the Termination Form will be sent to the Second Fiduciary for the Client Plan upon request.

(1) The Second Fiduciary receives full written disclosure, prior to the effective date, in a Fund prospectus or otherwise, of any increases in the rates of fees charged by Comerica to the Funds for investment advisory services even though such fees will be rebated as required by paragraph (d) above.

(m) In the event that Comerica provides an additional Secondary Service to a Fund for which a fee is charged or there is an increase in the rate of any fee paid by the Funds to Comerica for any Secondary Services that results from either an increase in the rate of such fee or a decrease in the number or kind of services performed by Comerica for such fees in connection with a previously authorized Secondary Service, Comerica will, at least 30 days in advance of the implementation of such additional service for which a fee is charged or fee increase, provide written notice (that is separate from the prospectus of the Fund) to the Second Fiduciary explaining the nature and the amount of the additional services or of the effective increase in fees of the affected Fund. Such notice shall be accompanied by the Termination Form.

(n) On an annual basis, Comerica provides the Second Fiduciary of a Client Plan investing in the Funds with: A copy of the current prospectus for the Funds and, upon such Second Fiduciary's request, a copy of the Statement of Additional Information for such Funds that contains a description

of all fees paid by the Funds to Comerica (including fees for investment advisory service);

(2) A copy of the annual financial disclosure report of the Funds in which such Client Plan is invested, which includes information about the Fund portfolios, within 60 days of the preparation of the report; and

(3) Oral or written responses to inquiries of the Second Fiduciary as they arise.

(o) All dealings between the Client Plans and the Funds are on a basis no less favorable to the client Plans than dealings with other shareholders of the Funds.

Section II. General Conditions

(a) Comerica maintains for a period of six years the records necessary to enable the persons described in paragraph (b) of Section II to determine whether the conditions of this exemption have been met, except that: a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of Comerica, the records are lost or destroyed prior to the end of the six-year period, and no party in interest other than Comerica shall be subject to the civil penalty that may be assessed under section 502(i) of ERISA or to the taxes imposed by section 4975(a) and (b) of the Code if the records are not maintained or not available for examination as required by paragraph (b) below.

(b)(1) Except as provided in paragraph (b)(2) below and notwithstanding any provisions of sections 504(a)(2) and (b) or ERISA, the records referred to in paragraph (a) of Section II are unconditionally available at their customary location for examination during normal business hours by: (1) Any duly authorized employee or representative of the Department of Labor or the Internal Revenue Service; (ii) Any fiduciary of a Client Plan who has authority to acquire or dispose of shares of the Funds owned by the Client Plan, or any duly authorized employee or representative of such fiduciary; and (iii) Any participant or beneficiary of a Client Plan or duly authorized employee or representative of such participant or beneficiary.

(2) None of the persons described in subparagraph (b)(1)(ii) and (iii) above shall be authorized to examine trade secrets of Comerica, or commercial or financial information, which is privileged or confidential.

Section III—Definitions

For purposes of this exemption:

(a) ''Comerica'' means Comerica Bank, a Michigan banking corporation, and any affiliate thereof (as affiliate is defined below in paragraph (b) of this section).

(b) an ''affiliate'' of a person includes:

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee, relative, or partner in any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(c) ''Control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(d) The term ''Fund'' or ''Funds'' shall include the Munder Funds, each series thereof, or any other diversified open-end investment company registered under the 1940 Act for which Comerica serves as an investment adviser and may also serve as a Fund accountant, transfer agent or provide some other Secondary Service (as defined below in paragraph (h) of Section III) which has been approved by such Funds.

(e) ''Net asset value'' means the amount for purposes of pricing all purchases and sales, calculated by dividing the value of all securities, determined by a method as set forth in a Fund's prospectus and statement of additional information, and other assets belonging to the Fund or portfolio of the Fund, less the liabilities charged to each such portfolio or Fund, by the number of outstanding shares.

(f) ''Relatives'' means a ''relative'' as that term is defined in section 3(15) of ERISA (or a ''member for the family'' as that term is defined in section 4975(e)(6) of the Code), or a brother, a sister, or a spouse of a brother or a sister.

(g) ''Second Fiduciary'' means a fiduciary of a Client Plan who is independent of and unrelated to Comerica. For purposes of this exemption, the Second Fiduciary will not be deemed to be independent of and unrelated to Comerica if:

(1) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with Comerica;

(2) Such fiduciary, or any officer, director partner, employee, or relative of the fiduciary is an officer, director, partner, or employee of Comerica (or is a relative of such persons); or

(3) Such fiduciary directly or indirectly receives any compensation or other consideration for his or her own personal account in connection with any transaction described in this exemption.

If an officer, director, partner, or employee of Comerica (or relative of such persons), is a director of such Second Fiduciary, and if he or she abstains from participation in (i) the choice of the Client Plan's investment adviser, (ii) the approval of any such purchase or sale between the Client Plan the Funds, and (iii) the approval of any change in fees charged to or paid by the Client Plan in connection with any of the transactions described in Section I and Section II above, then subparagraph (g)(2) of Section III shall not apply.

(h) ''Secondary Service'' means a service other than an investment management, investment advisory, or similar services which is provided by Comerica to the Funds including but not limited to) custodian services, transfer and dividend disbursing agent services, administrator or sub-administrator services, accounting services, and shareholder servicing agent services.

However, for purposes of this exemption, the term ''Secondary Service'' will not include any brokerage services provided to the Funds by Comerica for the execution of securities transactions engaged in by the Funds.

(i) ''Termination form'' means the form supplied to the second Fiduciary that expressly provides an election to the Second Fiduciary to terminate on behalf of a Client Plan the authorization described in paragraph (j) of Section I above. Such Termination Form maybe used at will by the Second Fiduciary to terminate an authorization without penalty to the Plan and to notify Comerica in writing to effect a termination by selling the shares of the funds held by the Client Plan requesting such termination within one business day following receipt by Comerica of the form provided that if, due to circumstances beyond the control of Comerica, the sale cannot be executed within one business day, Comerica shall have one additional business day to complete such sale.

DATES: This exemption is effective on or after November 24, 2004.

The Department received no comments or requests for a public hearing. After giving full consideration to the entire record, the Department has decided to grant the exemption. For a more complete statement of the facts and representations supporting he Department's decision to grant this exemption, refer to the notice of proposed exemption published on September 10, 2004, at 69 FR 54804.

For information regarding the matters described herein, interested persons are encouraged to obtain copies of the exemption application file (Exemption

Application No. D–11098) the Department is maintaining in this case. The complete application file is available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, Room N–1513, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

For Further Information Contact: Ms. Wendy McColough of the Department, telephone (202) 693–8561. This is not a toll-free number.

Camino Medical Group, Inc. matching 401(k) Plan (the 401(k) Plan) and the Camino Medical Group, Inc. Employee Retirement Plan (the Retirement Plan; together, the Plans) Located in Sunnyvale, California.

[Prohibited Transaction Exemption 2004–21; Exemption Application Nos. D–11160 & D–11161, respectively]

Exemption

The restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not reply to (1) the leasing (the New Lease) of a medical treatment center (the Treatment Center) by the Retirement Plan to Camino Medical Group, Inc. (CMG), the sponsor of the Retirement Plan and a party in interest with respect to such Retirement Plan; and (2) the exercise, by CMG, of options to renew the New Lease for two additional terms.

This exemption is subject to the following conditions:

(a) The terms and conditions of the New Lease are no less favorable to the Retirement Plan than those obtainable by the Retirement Plan under similar circumstances when negotiated at arm's length with unrelated third parties.

(b) The Retirement Plan is represented for all purposes under the New Lease, and during each renewal term, by a qualified, independent fiduciary.

(c) The Retirement Plan's independent fiduciary has negotiated, reviewed, and approved the terms and conditions of the New Lease and the options to renew the New Lease on behalf of the Retirement Plan and has determined that the transactions are appropriate investments for the Retirement Plan and are in the best interests of the Retirement Plan and its participants and beneficiaries.

(d) The rent paid to the Retirement Plan under the New Lease, and during each renewal term, is no less than the fair market rental value of the Treatment Center, as established by a qualified, independent appraiser.

(e) The rent is subject to adjustment at the commencement of the second year of the term of the New Lease and each year thereafter by way of an independent appraisal. A qualified, independent appraiser is selected by the independent fiduciary to conduct the appraisal. If the appraised fair market rent of the Treatment Center is greater than that of the current base rent, then the base rent is revised to reflect the appraised increased in fair market rent. If the appraised fair market rent of the Treatment Center is less than or equal to the current base rent, then the base rent remains the same.

(f) The New Lease is triple net and requires all expenses for maintenance, taxes, utilities and insurance to be paid by CMG, as lessee.

(g) The Retirement Plan's independent fiduciary monitors compliance with the terms of the New Lease and the conditions of the exemption throughout the duration of the New Lease and each renewal term, and is responsible for legally enforcing the payment of the rent and the proper performance of all other obligations of CMG under the terms of the New Lease.

(h) The Retirement Plan's independent fiduciary expressly approves any renewal of the New Lease beyond the initial term.

(i) CMG provides the Retirement Plan's independent fiduciary with documentation that the rent has been paid on a monthly basis.

(j) At all times throughout the duration of the New Lease and each renewal term, the fair market value of the Treatment Center does not exceed 25 percent of the value of the total assets of the Retirement Plan.

(k) CMG files a Form 5330 with the Internal Revenue Service (the Service) and pays all applicable excise taxes, if any, within 90 days of the publication, in the **Federal Register,** of the grant notice with respect to the leasing of the Treatment Center by the Plans to CMG prior to July 1, 2003.

(l) To the extent CMG owes the 401(k) Plan or the Retirement Plan additional rent by reason of the past leasing of the Treatment Center, (i) the independent fiduciary makes all such determinations, including the payment of reasonable interest; and (ii) CMG makes such payments to the Plans.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on July 20, 2004, at 69 FR 43438.

Extension of Comment Period

The notice of proposed exemption invited interested persons to submit comments or requests for a hearing to the Department by September 3, 2004. The applicant agreed to provide notice to interested persons by first class mail within ten days of the date that the proposal appeared in the **Federal Register**. CMG had valid addresses for all but 28 interested persons, all of whom were former employees of CMG with interests in one or both Plans. CMG submitted those 28 names to a commercial locating service, and received addresses for 23 of them. Notice was sent by first class mail to all but the 5 ''missing'' interested persons on July 26, 2004.

CMG submitted the Social Security Numbers of the 5 ''missing'' interested persons to a second commercial locating service. The notice was sent by first class mail to the last known address provided by the second commercial locating service for these five individuals on July 29, 2004.

On September 2, 2004, the applicant decided to extend the comment period until September 10, 2004. The need for the extension arose because the applicant changed legal representation with respect to this exemption and therefore required additional time to provide its comments to the Department.

Written Comments

During the comment period, the Department received one written comment with respect to the proposed exemption, and no requests for public hearing. The comment, which was submitted by CMG, is intended to (1) inform the Department of certain historical substantive and procedural matters related to the exemption; (2) request retroactive relief with respect to the exemption; and (3) correct minor errors in the proposal. In this regard, CMG has provided the following additional information in order to update the proposed exemption and to support its request for retroactive relief:

1. *History of Lease of Treatment Center by CMG.* Representation 9 of the Summary of Facts and Representations (the Summary) states, in relevant part, that the 401(k) Plan and Advanced Infusion Systems (AIS), an unrelated party, entered into a new lease for the Treatment Center for a 5 year term, from March 1, 1993 through February 28, 1998. Representation 10 of the Summary further states, in pertinent part, that before the end of the lease term, the Administrative Committee for the Plans (the Administrative Committee) and AIS

engaged in discussions relating to the renewal of the lease of the Treatment Center and that the Administrative Committee anticipated that AID would renew the lease. However, Representation 10 of the Summary states that at the end of February 1998, AIS chose not to renew its lease and vacated the premises, and that on March 1, 1998, CMG stepped into the shoes of AIS in order to continue the flow of rental income and the provision of infusion therapy to the CMG patients.

CMG confirms that, in regard to the history of its lease of the Treatment Center, an unrelated third party which was leasing the Treatment Center unexpectedly abandoned the Treatment Center at the end of February 1998 and did not renew its lease. CMG explains that it believed the most prudent course of action was for it to immediately lease the Treatment Center (a medical clinic) from the 401(k) Plan. CMG opines that in leasing the Treatment Center it could (a) continue to provide its patients with infusion therapy for AIDS patients, and (b) continue to provide the 401(k) Plan with $9,500 in monthly rental income. CMG notes that it was informed that it might take months for the 401(k) Plan to find a tenant for the medical clinic. CMG states that it did not consider it prudent, either financially for the 401(k) Plan or with regard to treating its patients, to have the Treatment Center empty for that period of time.

Notwithstanding the exigent circumstances precipitating CMG's leasing of the Treatment Center from the 401(k) Plan in 1998 and CMG's goodwill intentions, the Department wishes to emphasize that the lease became a prohibited transaction in violation of the Act at the moment CMB assumed lessee responsibilities. Due to the absence of adequate independent safeguards existing at the inception of the lease, CMB has represented that it will file a Form 5330 with the Service and pay all applicable excise taxes that may be due by virtue of its prohibited leasing arrangement with the 401(k) Plan and subsequently, with the Retirement Plan.

2. *Attorney's Concealment of Lack of Action on Application for Exemption.* CMG states that although it instructed its attorney to apply for a prohibited transaction exemption immediately to cover its lease of the Treatment Center on March 1, 1998, the attorney did not file an application for an exemption until December 1999. CMG explains that after the initial filing, the attorney did not follow up with requests by the Department for additional information. Consequently, CMG states, a second application was required to be made. CMG represents that the second application was filed in November 2001, almost two years after the first application was filed. CMG notes that even after filing the second application, the attorney did not comply promptly with the Department's request for additional information, resulting in additional delay publishing in the proposed exemption in the **Federal Register**. CMG represents that it had no knowledge, or ability to know, of the attorney's dilatory actions since the fact that the attorney was not proceeding on this matter was not disclosed to CMG. CMG states that it was assured at all times that each of the exemption requests was in progress.

The Department can take no remedial action to remedy any harm CMG may have suffered. The Department notes that any grievance CMG may have against its former counsel should be addressed in the appropriate legal forum.

3. *Retroactive Effect of Exemption.* Representation 14 of the Summary states in relevant part that—

> Due to the lack of oversight by a qualified, independent fiduciary with full investment discretion to review, approve and monitor the past and continuing leasing arrangements between the Plans and CMG, and the absence of contemporaneous independent appraisals establishing the fair market value or the fair market rental value of the Treatment Center at the inception of each lease or at the time of the sale of the Treatment Center by the 401(k) Plan to the Retirement Plan, the Department is not prepared to provide exemptive relief with respect to such transactions.

CMG notes that ERISA Technical Release 85–1 (TR 85–1) provides that if the applicant has acted in good faith (evidenced by an independent fiduciary or appraisal) and there was no loss to the plan in question the Department may favorably consider making a prohibited transaction exemption retroactive. CMG explains that all the conditions set out in TR 85–1 for a retroactive exemption are present in this case. Consequently, CMG requests that the exemption be made retroactive to November 1998, which is the date of the first appraisal of the fair market rental value of the Treatment Center after it was leased by CMG. CMG explains that the appraisal was done by a qualified independent appraiser, Hulberg & Associates (Hulberg), under the direction of two independent fiduciaries.

CMG further explains that the first lease agreement covering the lease of the Treatment Center to CMG was dated March 1, 1999. The fair market rental value of that lease was also determined by Hulberg, under the direction of the same independent trustees. The March 1999 lease provided for rental increases (if any) each year based on an annual appraisal by the independent appraiser of market rents. Because the rental market went up and then went down for several years, under the lease agreement CMG states that it paid in excess of market rates each year except one. CMG also maintains that not only was there no loss to participants in the rental transaction, there was a significant gain. In July 2003, CMG explains that a second lease was signed for the Treatment Center. In that case, the independent fiduciary was Thomas J. Nault and the independent appraiser chosen by Mr. Nault was also Hulberg. CMG indicates that Mr. Nault has continued to serve on behalf of the Retirement Plan as the independent fiduciary.

CMG maintains that in both leases covering the Treatment Center, there was an independent appraisal of the fair market rental value of such property. Also, CMG asserts that the appraisals were under the direct supervision of independent fiduciaries. Although CMG believes the conditions are present for the exemption to be made retroactive to November 1998, at the very minimum, CMG suggest that the exemption be made retroactive to March 1, 1999, or July 1, 2003, the commencement dates of the leases, or retroactive to March 2003, the date of Mr. Nault's appointment as independent trustee for the Retirement Plan.

As an additional factor, CMG requests that the Department consider that prior to Mr. Nault's assumption of independent fiduciary duties, at all times since the Treatment Center was leased to CMG, Wells Fargo Bank, N.A. (Wells Fargo), has been the trustee of the Retirement Plan. Although the bank was and is a directed trustee, CMG states that it has provided the Department with a letter from Wells Fargo which states that the bank reviewed the Treatment Center's lease appraisal for reasonableness and adjusted the monthly rental income, accordingly. CMG notes that Wells Fargo also stated that it reviewed the terms of the leases to ensure compliance and to ensure that lease payments were received and deposited to the trust in a timely manner each month.

In response to CMG's comment, the Department wishes to emphasize that further distinctions must be made to the independent fiduciary and independent appraisal criteria set forth in TR 85–1. This is because the safeguards implemented for a prospective exemption must be in place for a

retroactive exemption. In this regard, the Department does not believe the lease can be made retroactive to March 1, 1999,[1] due to the lack of adequate independent safeguards. Specifically, there was no contemporaneous appraisal or other objective means to establish the fair market rental value of the Treatment Center at the inception of the 1999 lease, despite the fact that CMG has, for the most part, paid the CMG Plans more than fair market value rent. The Department notes that the only written independent appraisal of the Treatment Center existing at that time was issued by Hulberg on December 20, 1998. The appraisal, which was commissioned primarily for the sale of the Treatment Center by the 401(k) Plan to the Retirement Plan reflected, among other things, the fair market rental value of the Treatment Center as of November 24, 1998. Due to its relative staleness and the absence of documentation in the application file showing that an updated appraisal was obtained on the date the parties entered into the 1999 lease, the 1998 appraisal could not be utilized to substantiate the fair market value of the Treatment Center at the inception of the 1999 lease. Further, although Wells Fargo may have represented the interests of the 401(k) Plan and later the Retirement Plan, the Department notes that there is not indication that the bank ever possessed ''full'' discretion as an independent fiduciary with respect to the approval and monitoring the leasing of Treatment Center or advising CMG that it would be engaged in a prohibited transaction.

Similarly, it appears that the lease cannot be made retroactive to March 1, 2003. This is the date that Mr. Nault was appointed as the Retirement Plan's successor independent fiduciary. Again, the Department believes that independent safeguards to protect the interests of the Retirement Plan and its participants and beneficiaries were lacking. Although Mr. Nault was then serving as the independent fiduciary, his appointment could not be utilized to validate the lease, which was already in existence.

With respect to the July 1, 2003, retroactivity date, Mr. Nault has provided the Department with certain additional information. In a letter dated October 7, 2004, Mr. Nault states that a new lease (*i.e.*, the ''New Lease'' referred to above in the operative language) of the Treatment Center was executed between CMG and the Retirement Plan on July 1, 2003, at the time the New Lease was executed, he explains that he relied on other objective means of valuation to determine the fair market rental value of the Treatment Center at the time this lease was executed. Such objective means included several discussions with Hulberg in order to ascertain the fair market rental value of the Treatment Center and due diligence conducted from the time of his independent fiduciary appointment onward. Specifically, Mr. Nault explains that during his discussions with Hulberg, he reviewed rental statistics for the Sunnyvale-San Jose area that clearly showed that the rent being paid for the Treatment Center was above market. Further, as part of his own due diligence, Mr. Nault states that he drove around the area to check the vacancy information he received from Hulberg, he did an online analysis of rents and market conditions to ascertain rent levels in the area, and researched the effect of the 2001 implosion of Dot-Com businesses on the office vacancy rate in that area. Mr. Nault states that his findings at the time the New Lease was executed indicated that CMG was paying above market rent prior to such lease. Consequently, Mr. Nault represents that the rental amount being paid by CMB under the New Lease provides that the rent will be changed only if the amount that CMG is paying falls below market value.

Although there was no contemporaneous, written appraisal of the Treatment Center at the inception of the New Lease, the Department believes that Mr. Nault has demonstrated that he utilized an objective means of valuation of the Treatment Center immediately prior to, and at the time of, the New Lease by analyzing the prevailing market conditions. In addition, the Department notes that for assistance, Mr. Nault obtained significant guidance from Hulberg, the Retirement Plan's independent appraiser. Therefore, the Department believes that adequate independent safeguards existed at the inception of the New Lease. Accordingly, the Department has determined that the exemption should be made retroactive to July 1, 2003.

In addition, in order that the operative language of the exemption may be consistent with the July 1, 2003, effective date, the Department has modified conditions (f), (k) and (l) of the final exemption to read as follows:

(f) The New Lease is triple net and requires all expenses for maintenance, taxes, utilities and insurance to be paid by CMG, as lessee.

(k) CMG files a Form 5330 with the Internal Revenue Service (the Service) and pays all applicable excise taxes, if any, within 90 days of the publication, in the Federal Register, of the grant notice with respect to the leasing of the Treatment Center by the Plans to CMG prior to July 1, 2003.

(l) To the extent CMG owes the 401(k) Plan or the Retirement Plan additional rent by reason of the past leasing of the Treatment Center, (i) the independent fiduciary makes all such determinations, including the payment of reasonable interest; and (ii) CMG makes such payments to the Plans.

4. *Miscellaneous Comments.* CMG notes that the caption of the proposed exemption states, in relevant part, that the Plans are located in Santa Clara, California. CMG clarifies that the Plans are located in ''Sunnyvale (County of Santa Clara), California.''

In addition, Representation 1 of the Summary states, in pertinent part, that CMG is a ''not-for-profit'' organization. CMG explains that it is a ''for-profit'' organization and that the Palo Alto Medical Foundation, of which CMG is an affiliate, is a ''not-for-profit'' organization.

Further, Representation 13 of the Summary states, in relevant part, that CMG presently leases the Treatment Center and pays a monthly rental of $1,456. CMG notes that the monthly rental which it currently pays the Retirement Plan for its lease of the Treatment Center is $14,256.

In response to the foregoing comments, the Department notes the clarifications to the proposed exemption.

Accordingly, after giving full consideration to the entire record, including the comment letter, the Department has determined to grant the exemption as modified herein. For further information regarding the comment, additional information provided by the independent fiduciary, and other matters discussed herein, interested persons are encouraged to obtain copies of the exemption application file (Exemption Application Nos. D–11160 and D–11161) the Department is maintaining in this case. The complete application file, as well as all supplemental submissions received by the Department, are made available for public inspection in the Public Disclosure Room of the Pension and Welfare Benefits Administration, Room N–1513, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

For Further Information Contact: Ms. Anna M.N. Mpras of the Department, telephone (202) 693–8565. (This is not a toll-free number.)

[1] In this regard, the lease had actually been entered into by CMG and the 401(k) Plan, the previous owner of the Treatment Center on March 1, 1998. However, that lease, which was executed by the Retirement Plan (the current owner of the Treatment Center) and CMG, was not reduced to writing until March 1, 1999.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) This exemption is supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of this exemption is subject to the express condition that the material facts and representations contained in the application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed in Washington, DC, this 19th day of November, 2004.

Ivan Strasfeld,

Director of Exemption Determinations, Employee Benefits Security Administration, Department of Labor.

[FR Doc. 04–26068 Filed 11–23–04; 8:45 am]

BILLING CODE 4510–29–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR 1218–0075(2005)]

Fire Brigades Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comment.

SUMMARY: OSHA solicits public comment concerning its request for an extension of the information collection requirements contained in the Fire Brigades Standard (29 CFR 1910.156).

DATES: Comments must be submitted by the following dates:

Hard Copy: Your comments must be submitted (postmarked or received) by January 24, 2005.

Facsimile and electronic transmission: Your comments must be received by January 24, 2005.

ADDRESSES: You may submit comments, identified by OSHA Docket No. ICR–1218–0075(2005), by any of the following methods:

Regular mail, express delivery, hand delivery, and messenger service: Submit your comments and attachments to the OSHA Docket Office, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). OSHA Docket Office and Department of Labor hours are 8:15 a.m. to 4:45 p.m., e.t.

Facsimile: If your comments are 10 pages or fewer in length, including attachments, you may fax them to the OSHA Docket Office at (202) 693–1648.

Electronic: You may submit comments through the Internet at *http://ecomments.osha.gov*. Follow instructions on the OSHA Web page for submitting comments.

Docket: For access to the docket to read or download comments or background materials, such as the complete Information Collection Request (ICR) (containing the Supporting Statement, OMB–83–I Form, and attachments), go to OSHA's Web page at *http://www.OSHA.gov*. In addition, comments, submissions and the ICR are available for inspection and copying at the OSHA Docket Office at the address above. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

(For additional information on submitting comments, please see the ''Public Participation'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.)

FOR FURTHER INFORMATION CONTACT: Theda Kenney, Directorate of Standards and Guidance, OSHA, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments and supporting materials in response to this notice by (1) hard copy, (2) FAX transmission (facsimile), or (3) electronically through the OSHA Web page. Because of security related problems, there may be a significant delay in the receipt of comments by regular mail. Please contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for information about security procedures concerning the delivery of submissions by express delivery, hand delivery and courier service.

All comments, submissions and background documents are available for inspection and copying at the OSHA Docket Office at the above address. Comments and submissions posted on OSHA's Web page are available at *http://www.OSHA.gov*. Contact the OSHA Docket Office for information about materials not available through the OSHA Web page and for assistance using the Web page to locate docket submissions.

Electronic copies of this **Federal Register** notice as well as other relevant documents are available on OSHA's Web page.

II. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657).

Although OSHA does not mandate that employers establish fire brigades, if they do so, they must comply with the provisions of the Standard. The provisions of the Standard, including the paperwork requirements, apply to fire brigades, industrial fire departments, and private or contract fire departments, but not to airport crash-rescue units or forest fire-fighting operations. Paragraphs (b)(1), (b)(2), (c)(2), and (c)(4) contain the paperwork requirements of the Standard.

Under paragraph (b)(1) of the Standard, employers must develop and maintain an organizational statement that establishes the: Existence of a fire brigade; the basic organizational structure of the brigade; type, amount, and frequency of training provided to brigade members; expected number of members in the brigade; and functions that the brigade is to perform. This paragraph also specifies that the organizational statement must be available for review by employees, their designated representatives, and OSHA compliance officers. The organizational statement delineates the functions performed by the brigade members and, therefore, determines the level of training and type of personal protective equipment (PPE) necessary for these members to perform their assigned functions safely. Making the statement available to employees, their designated representatives, and OSHA compliance officers ensures that the elements of the statement are consistent with the functions performed by the brigade members and the occupational hazards they experience, and that employers are providing training and PPE appropriate to these functions and hazards.

To permit an employee with known heart disease, epilepsy, or emphysema to participate in fire brigade emergency activities, paragraph (b)(2) of the Standard requires employers to obtain a physician's certificate of the employee's fitness to do so. This provision provides employers with a direct and efficient means of ascertaining whether or not they can safely expose employees with these medical conditions to the hazards of fire-fighting operations.

Paragraph (c)(1) of the Standard requires employers to provide training and education for fire brigade members commensurate with the duties and functions they perform, with brigade leaders and training instructors receiving more comprehensive training and education than employers provide to the general membership. Under paragraph (c)(2) of the Standard, employers must conduct training and education frequently enough, but at least annually, to assure that brigade members are able to perform their assigned duties and functions satisfactorily and safely; employers must provide members who perform interior structural fire-fighting with educational and training sessions at least quarterly. In addition, paragraph (c)(4) specifies that employers must: Inform brigade members about special hazards such as storage and use of flammable liquids and gases, toxic chemicals, radioactive sources, and water-reactive substances that may be present during fires and other emergencies; advise brigade members of changes in the special hazards; and develop written procedures that describe the actions brigade members must take when special hazards are present, and make these procedures available in the education and training program and for review by the brigade members.

Providing appropriate training to brigade members at the specified frequencies, informing them about special hazards, developing written procedures on how to respond to special hazards, and making these procedures available for training purposes and review by the members enables them to use operational procedures and equipment in a safe manner to avoid or control dangerous exposures to fire-related hazards. Therefore, the training and information requirements specified by paragraphs (c)(1), (c)(2), and (c)(4) of the Standard prevent serious injuries and death among members of fire brigades.

III. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

IV. Proposed Actions

OSHA proposes to extend the Office of Management and Budget's (OMB) approval of the collection of information (paperwork) requirements in the Fire Brigades Standard (29 CFR 1910.156). The Agency will include this summary in its request to OMB to extend the approval of these collection of information requirements.

Type of Review: Extension of currently approved information collection requirements.

Title: Fire Brigades (29 CFR 1910.156).

OMB Number: 1218–0075.

Affected Public: Business or other for-profits; Not-for-profit organizations; Federal Government; State, local or tribal government.

Number of Respondents: 55,939.

Frequency: On occasion.

Average Time Per Response: Varies from 5 minutes (.08 hour) to 2 hours.

Estimated Total Burden Hours: 6.042.

Estimated Cost (Operation and Maintenance): $0.

V. Authority and Signature

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*), and Secretary of Labor's Order No. 5–2002 (67 FR 65008).

Signed at Washington, DC, on November 18th, 2004.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 04–26044 Filed 11–23–04; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. NRTL1–90]

Communication Certification Laboratory, Application for Renewal and Expansion of Recognition; Withdrawal of Sites of Other NRTLs

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice announces the application of Communication Certification Laboratory, Inc., for renewal of its recognition as a Nationally Recognized Testing Laboratory and for expansion of its recognition to use additional test standards. This notice also presents the Agency's preliminary finding. This preliminary finding does not constitute an interim or temporary approval of these applications. In an unrelated matter, this notice also announces the voluntary withdrawals of recognition of the Electrical Reliability Services, Inc., (formerly Electro-Test, Inc.) site located in Brea, California, and the SGS U.S. Testing Company site located in Los Angeles, California.

DATES: You may submit comments in response to the expansion application portion of this notice, or any request for extension of the time to comment, by (1) Regular mail, (2) express or overnight delivery service, (3) hand delivery, (4) messenger service, or (5) FAX transmission (facsimile). Because of security-related problems there may be

a significant delay in the receipt of comments by regular mail. Comments (or any request for extension of the time to comment) must be submitted by the following dates:

Regular mail and express delivery service: Your comments must be postmarked by December 9, 2004.

Hand delivery and messenger service: Your comments must be received in the OSHA Docket Office by December 9, 2004. OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m.

Facsimile and electronic transmission: Your comments must be sent by December 9, 2004.

ADDRESSES: Regular mail, express delivery, hand-delivery, and messenger service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket NRTL1–90, Room N–2625, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, NW., Washington, DC 20210. Please contact the OSHA Docket Office at (202) 693–2350 for information about security procedures concerning the delivery of materials by express delivery, hand delivery and messenger service.

Facsimile: If your comments, including any attachments, are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648. You must include the docket number of this notice, Docket NRTL1–90, in your comments.

Internet access to comments and submissions: OSHA will place comments and submissions in response to this notice on the OSHA Web page *http://www.osha.gov*. Accordingly, OSHA cautions you about submitting information of a personal nature (*e.g.*, social security number, date of birth). There may be a lag time between when comments and submissions are received and when they are placed on the Web page. Please contact the OSHA Docket Office at (202) 693–2350 for information about materials not available through the OSHA Web page and for assistance in using the Web page to locate docket submissions. Comments and submissions will also be available for inspection and copying at the OSHA Docket Office at the address above.

Extension of Comment Period: Submit requests for extensions concerning this notice to: Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, Room N3653, 200 Constitution Avenue, NW., Washington, DC 20210. Or fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Sherrey Nicolas, Office of Technical Programs and Coordination Activities, NRTL Program, Room N3653 at the address shown immediately above for the program, or phone (202) 693–2110.

SUPPLEMENTARY INFORMATION:

Notice of Application

The Occupational Safety and Health Administration (OSHA) hereby gives notice that Communication Certification Laboratory, Inc. (CCL), has applied for renewal and for expansion of its recognition as a Nationally Recognized Testing Laboratory (NRTL). CCL's expansion requests cover the use of additional test standards. OSHA's current scope of recognition for CCL may be found in the following informational Web page: *http://www.osha-slc.gov/dts/otpca/nrtl/ccl.html*.

OSHA recognition of an NRTL signifies that the organization has met the legal requirements in § 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products ''properly certified'' by the NRTL to meet OSHA standards that require testing and certification.

The Agency processes applications by an NRTL for initial recognition or for expansion or renewal of this recognition following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. We maintain an informational Web page for each NRTL, which details its scope of recognition. These pages can be accessed from our Web site at *http://www.osha-slc.gov/dts/otpca/nrtl/index.html*.

The most recent notices published by OSHA for CCL's recognition covered its prior renewal of recognition, which became effective on April 2, 1998 (63 FR 16279).

The current address of the CCL facility (site) already recognized by OSHA is: Communication Certification Laboratory, Inc., 1940 West Alexander Street, Salt Lake City, Utah 84119.

General Background on the Applicant and Applications

Communication Certification Laboratory (CCL) initially received OSHA recognition as a Nationally Recognized Testing Laboratory on June 21, 1991 (56 FR 28579) for a five-year period ending on June 21, 1996. CCL properly requested a renewal of recognition, and OSHA granted CCL first renewal on April 2, 1998 (63 FR 16279) for another five-year period ending April 2, 2003.

Appendix A to 29 CFR 1910.7 stipulates that the period of recognition of an NRTL is five years and that an NRTL may renew its recognition by applying not less than nine months, nor more than one year, before the expiration date of its current recognition. NRTLs submitting requests within this allotted time period retain their recognition during OSHA's renewal process. CCL has submitted a request, dated June 26, 2002 (*see* exhibit 11), to renew its recognition, within the allotted time period, and retains its recognition pending OSHA's final decision in this renewal process. CCL's existing scope of recognition consists of the facility listed above, and the test standards and supplemental programs listed below under *Renewal of Recognition*.

In its request, CCL also requested expansion of its recognition to include three additional test standards but amended its request to just two additional standards, which the NRTL Program staff has determined to be appropriate test standards, within the meaning of 29 CFR 1910.7(c). (The staff makes similar determinations in processing expansion requests from any NRTL.) Therefore, OSHA would approve the two test standards for the expansion, which are listed below under *Expansion of Recognition*.

For purposes of processing CCL's request, OSHA NRTL Program staff performed two on-site reviews of CCL's facility on October 29–30, 2003, and November 18–20, 2002. In the memo for the on-site reviews (*see* Exhibit 12), the staff recommended CCL's renewal and its expansion to include the two test standards requested.

Renewal of Recognition

CCL seeks renewal of its recognition for the one site that OSHA currently includes within the NRTL's scope. CCL also seeks renewal of its recognition for testing and certification of products for demonstration of conformance to the following four test standards, which OSHA has previously recognized for CCL. Two of those standards, UL 1459

and UL 1950, have been withdrawn by the standards developing organization. However, since the scope of recognition of other NRTLs may include these standards, we are including them temporarily in the renewal. In the near future, we will publish another **Federal Register** notice in order to remove or replace these and other withdrawn standards, at the same time, from the scope of recognition of all applicable NRTLs.

UL1012 Power Units Other Than Class 2
UL 1459 Telephone Equipment
UL 1950 Safety of Information Technology Equipment, Including Electrical Business Equipment
UL 60950 Information Technology Equipment

OSHA's recognition of CCL, or any NRTL, for a particular test standard is limited to equipment or materials (*i.e.*, products) for which OSHA standards require third party testing and certification before use in the workplace. Consequently, an NRTL's scope of recognition excludes any product(s) falling within the scope of a test standard for which OSHA has no NRTL testing and certification requirements.

Many UL test standards also are approved as American National Standards by the American National Standards Institute (ANSI). However, for convenience, we use the designation of the standards developing organization for the standard as opposed to the ANSI designation. Under our procedures, any NRTL recognized for an ANSI-approved test standard may use either the latest proprietary version of the test standard or the latest ANSI version of that standard. You may contact ANSI to find out whether or not a test standard is currently ANSI-approved.

Programs and Procedures

The renewal would include CCL's continued use of any supplemental programs for which it is approved, based upon the criteria detailed in OSHA's March 9, 1995, **Federal Register** notice on the NRTL programs (60 FR 12980). This notice lists nine (9) programs, eight of which (called the supplemental programs) an NRTL may use to control and audit, but not actually to generate, the data relied upon for product certification. An NRTL's initial recognition will always include the first or basic program, which requires that all product testing and evaluation be performed in-house by the NRTL that will certify the product. OSHA has already recognized CCL for program(s) listed below. See *http://www.osha-slc.gov/dts/otpca/nrtl/ccl.html.*

Program 9: Acceptance of services other than testing or evaluation performed by subcontractors or agents.

OSHA developed these programs to limit how an NRTL may perform certain aspects of its work and to permit the activities covered under a program only when the NRTL meets certain criteria. In this sense, they are special conditions that the Agency places on an NRTL's recognition. OSHA does not consider these programs in determining whether an NRTL meets the requirements for recognition under 29 CFR 1910.7. However, these programs help to define the scope of that recognition.

Expansion of Recognition

CCL seeks recognition for two test standards, and OSHA has determined that the standards are appropriate, within the meaning of 29 CFR 1910.7(c).

UL 6500 Audio/Visual and Musical Instrument Apparatus for Household, Commercial, and Similar General Use
UL 61010A–1 Electrical equipment for measurement, control, and laboratory use

The NRTL Program staff did perform an on-site review in connection with the expansion request and provided a positive recommendation on the expansion (*see* Exhibit 12).

Preliminary Finding

CCL has submitted acceptable requests for renewal and expansion of its recognition as an NRTL. Our review of the application file, the on-site review reports, and other pertinent documents, indicates that CCL can meet the requirements, as prescribed by 29 CFR 1910.7, for: (1) The renewal for the one site and the test standards and program listed above, and (2) the expansion for the additional two test standards, also listed above. This preliminary finding does not constitute an interim or temporary approval of the application.

OSHA welcomes public comments, in sufficient detail, as to whether CCL has met the requirements of 29 CFR 1910.7 for the renewal and expansion of its recognition as a Nationally Recognized Testing Laboratory. Your comments should consist of pertinent written documents and exhibits. To consider a comment, OSHA must receive it at the address provided above (*see* **ADDRESSES**), no later than the last date for comments (*see* **DATES** above). Should you need more time to comment, OSHA must receive your written request for extension at the address provided above no later than the last date for comments. You must include your reason(s) for any request for extension. OSHA will limit any extension to 30 days, unless the requester justifies a longer period. We may deny a request for extension if it is frivolous or otherwise unwarranted. You may obtain or review copies of CCL's requests, the on-site review report, other exhibits, and all submitted comments, as received, by contacting the Docket Office, Room N2625, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address. You should refer to Docket No. NRTL1–90, the permanent record of public information on CCL's recognition.

The NRTL Program staff will review all timely comments and, after resolution of issues raised by these comments, will recommend whether to grant CCL's renewal and expansion requests. The Assistant Secretary will make the final decision on granting the renewal and expansion and, in making this decision, may undertake other proceedings that are prescribed in Appendix A to 29 CFR Section 1910.7. OSHA will publish a public notice of this final decision in the **Federal Register**.

Notice of Voluntary Termination

In an unrelated matter, Electrical Reliability Services, Inc., (formerly Electro-Test, Inc.) has requested that OSHA withdraw the recognition of the NRTL's site located in Brea, California (*see* docket NRTL2–94, Exhibit 15). This withdrawal is effective immediately, and OSHA will take no further action on it. OSHA recognized this site for ETI on October 6, 1995 (60 FR 52417), but, at the time, the site was in another city.

In addition, SGS U.S. Testing Company has requested that OSHA withdraw the recognition of the NRTL's site located in Los Angeles, California (*see* docket NRTL2–90, Exhibit 18). This withdrawal is effective immediately, and OSHA will take no further action on it. OSHA recognized this site for SGS on March 23, 1993 (58 FR 15509).

Under section II.D of Appendix A to 29 CFR 1910.7, OSHA must ''inform the public of any voluntary termination by **Federal Register** notice.'' These actions are unrelated to our preliminary finding on the CCL renewal and expansion request. We include them herein only for adminstrative convenience.

Signed at Washington, DC this 9th day of November, 2004.

John L. Henshaw,

Assistant Secretary.

[FR Doc. 04–26012 Filed 11–23–04; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL TRANSPORTATION SAFETY BOARD

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

The National Transportation Safety Board intends to submit the following (see below) public information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance under the paperwork reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). OMB approval is being requested concurrently with this submission. A copy of this individual ICR, with applicable supporting documentation, may be obtained by calling the National Transportation Safety Board Departmental Clearance Officer, Deborah Bruce (202) 314–6511. Comments and questions about the ICR listed below should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Transportation Safety Board, Office of Management and Budget, Room 10102, 725 17th Street, NW., Washington, DC 20503.

Agency: National Transportation Safety Board.

Title: Pilot/Operator Aircraft Accident/Incident Report.

OMB Number: 3147–0001.

Frequency: On occasion.

Affected Public: Individuals, businesses (for and not for profit), Governments (State, local, and Tribal).

Number of Respondents: 2,100.

Estimated time per respondent: 60 minutes.

Total Burden Hours: 2,100.

Description: The National Transportation Safety Board is required to investigate aviation accidents and certain incidents as stated in the 49 Code of Federal Regulations Part 830. Entities having a reportable accident/incident are required to report the details pertaining to the event to the Safety Board. To ensure pertinent data is collected, the Board uses a standard form for reporting the accident/incident.

The National Transportation Safety Board is seeking clearance to use the Pilot/Operator Aircraft Accident/Incident Report to help determine the facts, conditions, and circumstances of aviation accidents/incidents in order to facilitate prevention strategies and maintain statistics on aviation safety.

Dated: November 18, 2004.

Vicky D'Onofrio,

Federal Register Liaison Officer.

[FR Doc. 04–26053 Filed 11–23–04; 8:45 am]

BILLING CODE 7533–01–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection*: 10 CFR Part 61—Licensing Requirements for Land Disposal of Radioactive Waste.

2. *Current OMB approval number*: 3150–0135.

3. *How often the collection is required*: Applications for licenses are submitted as needed. Other reports are submitted annually and as other events require.

4. *Who is required or asked to report*: Applicants for and holders of an NRC license (to include Agreement States) for land disposal of low-level radioactive waste, and all generators, collectors, and processors of low-level waste intended for disposal at a low-level waste facility.

5. *The estimated number of annual respondents*: 4.

6. *The number of hours needed annually to complete the requirement or request*: 5,412 hours (56 hours for reporting {approximately 4.6 hours per response} plus 5,356 hours for recordkeeping {approximately 1,339 hours per recordkeeper}).

7. *Abstract*: Part 61 establishes the procedures, criteria, and license terms and conditions for the land disposal of low-level radioactive waste. Reporting and recordkeeping requirements are mandatory or, in the case of application submittals, are required to obtain a benefit. The information collected in the applications, reports, and records is evaluated by the NRC to ensure that the licensee's or applicant's physical plant, equipment, organization, training, experience, procedures, and plans provide an adequate level of protection of public health and safety, common defense and security, and the environment.

Submit, by January 24, 2005, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T–5 F52, Washington, DC 20555–0001, by telephone at 301–415–7233, or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV*.

Dated at Rockville, Maryland, this 17th day of November, 2004.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 04–26006 Filed 11–23–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–389]

St. Lucie Nuclear Power Plant, Unit 2; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–16, issued to Florida Power and Light Company (FPL, the licensee) for operation of the St. Lucie Nuclear Plant, Unit No. 2, located in St. Lucie County, Florida.

The proposed amendment would revise Technical Specification (TS) Section 4.4.5.4 to modify the definitions of steam generator tube ''Plugging

Limit'' and ''Tube Inspection,'' as contained in the St. Lucie Unit 2 TS Items 4.4.5.4.a.6 and 4.4.5.4.a.8, respectively. The purpose of these modifications is to define the depth of the required tube inspections and to clarify the plugging criteria within the tubesheet. The proposed amendment was submitted in response to the Commission Generic Letter 2004–01 and in support of the steam generator inspections planned during the upcoming St. Lucie Unit 2 refueling outage.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in Title 10 of the Code of Federal Regulations (10 CFR), Section 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

FPL proposes to modify the definitions of steam generator ''Plugging Limit'' and ''Tube Inspection,'' as contained in the St. Lucie Unit 2 Technical Specification (TS) Items 4.4.5.4.a.6 and 4.4.5.4.a.8, respectively. These modifications maintain existing design limits and would not increase the probability or consequences of an accident involving tube burst or primary to secondary accident-induced leakage, as previously analyzed in the UFSAR [Updated Final Safety Analysis Report]. Also, the tube burst criteria of NRC Regulatory Guide 1.121 (Basis for Plugging Degraded PWR [Pressurized Water Reactor] Steam Generator Tubes) would continue to be satisfied.

Tube burst is precluded for a tube with defects within the tubesheet region because of the constraint provided by the tubesheet. As such, tube pullout resulting from the axial forces induced by primary to secondary differential pressures would be a prerequisite for tube burst to occur. A joint industry test program (WCAP–16208–P) has defined the non-degraded tube to tubesheet joint length required to preclude tube pullout (C*) and maintain acceptable primary to secondary accident-induced leakage, assuming a 360° circumferential through wall crack existed immediately below this length. For St. Lucie Unit 2, C* is 10.1 inches. Any degradation below C* is shown by empirical test results and analyses to be acceptable, thereby precluding an event with consequences similar to a postulated tube rupture event. WCAP–16208–P incorporates an assumed primary to secondary accident-induced leakage value of 0.1 gpm/steam generator. Inspection to the C* length will ensure that the postulated accident induced leakage will remain below the current and future primary to secondary LCO leakage limits of 0.5 and 0.15 gpm/steam generator, respectively, imposed by the St. Lucie Unit 2 Technical Specifications (Section 3.4.6.2) and utilized in the UFSAR accident analyses (Chapter 15).

In summary, the proposed modifications to the St. Lucie Unit 2 Technical Specifications maintain existing design limits and do not involve a significant increase in the probability or consequences of an accident previously evaluated in the UFSAR.

2. Operation of the facility in accordance with the proposed amendments would not create the possibility of a new or different kind of accident from any previously evaluated.

Steam generator tube leakage and structural integrity will be maintained during all plant conditions upon implementation of the proposed inspection scope and plugging limit modifications to the St. Lucie Unit 2 Technical Specifications. These modifications do not introduce any new mechanisms that might result in a different kind of accident from those previously evaluated. Even with the limiting circumstances of a complete circumferential separation (360° through wall crack) of a tube below the C* length, tube pullout is precluded and leakage is predicted to be maintained within the Technical Specification limits during all plant conditions.

3. Operation of the facility in accordance with the proposed amendments would not involve a significant reduction in a margin of safety.

Upon implementation of the proposed inspection scope and plugging limit modifications to the St. Lucie Unit 2 Technical Specifications, operation with potential tube degradation below the C* inspection length within the tubesheet region of the steam generator tubing meets the margin of safety as defined by RG 1.121 (Basis for Plugging Degraded PWR Steam Generator Tubes) and RG 1.83 (Inservice Inspection of Pressurized Water Reactor Steam Generator Tubes), and the requirements of General Design Criteria 14, 15, 31 and 32 of 10 CFR 50. Therefore, the proposed modifications do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to

intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. (Note: Public access to ADAMS has been temporarily suspended so that security reviews of publicly available documents may be performed and potentially sensitive information removed. Please check the NRC Web site for updates on the resumption of ADAMS access.)If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestors/petitioner's interest. The petition must also identify the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HEARINGDOCKET@NRC.GOV;* or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to 301–415–3725 or by email to *OGCMailCenter@nrc.gov*. A copy of the request for hearing and petition for leave to intervene should also be sent to the M.S. Ross, Attorney, Florida Power and Light, P.O. Box 14000, Juno Beach, Florida 33408–0420, attorney for the licensee.

For further details with respect to this action, see the application for amendment dated November 8, 2004, which is available for public inspection at the Commission's PDR, located at One White Flint North, File Public Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. (Note: Public access to ADAMS has been temporarily suspended so that security reviews of publicly available documents may be performed and potentially sensitive information removed. Please check the NRC Web site for updates on the resumption of ADAMS access.)Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 18th day of November 2004.

For the Nuclear Regulatory Commission.

Brendan T. Moroney,

Project Manager, Section 2, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 04–26007 Filed 11–23–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting Notice

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on December 2–4, 2004, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Monday, November 21, 2003 (68 FR 65743).

Thursday, December 2, 2004, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10 a.m.: Expert Elicitation on Large-Break LOCA Frequencies (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the draft predecisional NUREG–XXX, ''Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process,'' and the conclusions and recommendations of the Expert Elicitation Panel.

10:15 a.m.–11:45 a.m.: Proposed Rule for Risk-Informing 10 CFR 50.46 (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the proposed rule for risk-informing 10 CFR 50.46, ''Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors.''

12:45 p.m.–2:45 p.m.: Technical Basis for Potential Revision of the Pressurized Thermal Shock (PTS) Screening Criteria in the PTS Rule (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the technical basis for potential revision of the PTS screening criteria in the PTS rule.

3 p.m.–4:30 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting.

4:45 p.m.–7 p.m.: Safeguards and Security Matters (Closed)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding safeguards and security matters.

Friday, December 3, 2004, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–9 a.m.: Peer Review Comments on the Technical Basis for Revising the PTS Screening Criteria (Open)—The Committee will hold discussions with the Chairman of the Peer Review Panel, as needed, regarding the Panel's comments on the technical basis for potential revision of the PTS screening criteria.

9 a.m.–10:30 a.m.: Draft Commission Paper on Technology Neutral Framework for Future Plant Licensing—Policy Issues (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the draft Commission Paper on ''Regulatory Structure for New Plant Licensing, Part 1: Technology Neutral Framework—Policy Issues.''

10:45 a.m.–11 a.m.: Subcommittee Report (Open)—The Committee will hear a report by the Chairman of the ACRS Subcommittee on Reliability and Probabilistic Risk Assessment regarding the status of development of the draft NUREG document on Treatment of Uncertainties.

11 a.m.–11:15 a.m.: Subcommittee Report (Open)—The Committee will hear a report by the Chairman of the ACRS Subcommittee on Plant License Renewal regarding interim review of the license renewal application for the Arkansas Nuclear One, Unit 2 Nuclear Power Plant.

11:15 a.m.–11:45 a.m.: Election of ACRS Officers for CY 2005 (Open)—The Committee will elect Chairman and Vice Chairman for the ACRS and Member-at-Large for the Planning and Procedures Subcommittee for CY 2005.

1:45 p.m.–2:45 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future meetings. Also, it will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, including anticipated workload and member assignments.

2:45 p.m.–3 p.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations (EDO) to comments and recommendations included in recent ACRS reports and letters. The EDO responses are expected to be made available to the Committee prior to the meeting.

3:15 p.m.–7 p.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will discuss proposed ACRS reports.

Saturday, December 4, 2004, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–12:30 p.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports.

12:30 p.m.–1 p.m.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of Committee activities and matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 5, 2004 (69 FR 59620). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Electronic recordings will be permitted only during the open portions of the meeting. Persons desiring to make oral statements should notify the Cognizant ACRS staff named below five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Cognizant ACRS staff prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

In accordance with Subsection 10(d) Pub. L. 92–463, I have determined that it is necessary to close portions of this meeting noted above to discuss and protect information classified as national security information and safeguards information pursuant to 5 U.S.C. 552b(c)(1) and (3).

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, as

well as the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Mr. Sam Duraiswamy, Cognizant ACRS staff (301–415–7364), between 7:30 a.m. and 4:15 p.m., e.t.

ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at pdr@nrc.gov, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html or http://www.nrc.gov/reading-rm/doc-collections/* (ACRS & ACNW Mtg schedules/agendas).

Videoteleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m., e.t., at least 10 days before the meeting to ensure the availability of this service.

Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the videoteleconferencing link. The availability of videoteleconferencing services is not guaranteed.

The ACRS meeting dates for Calendar Year 2005 are provided below:

ACRS meeting No.	Meeting dates
.....	January 2005 (No meeting).
519	February 10–12, 2005.
520	March 3–5, 2005.
521	April 7–9, 2005.
522	May 5–7, 2005.
523	June 1–3, 2005.
524	July 6–8, 2005.
.....	August 2005 (No meeting).
525	September 8–10, 2005.
526	October 6–8, 2005.
527	November 3–5, 2005.
528	December 8–10, 2005.

Dated: November 18, 2004.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 04–26005 Filed 11–23–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Opportunity To Comment on Model Safety Evaluation on Technical Specification Improvement To Modify Requirements Regarding the Addition of LCO 3.0.8 on the Inoperability of Snubbers Using the Consolidated Line Item Improvement Process

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for comment.

SUMMARY: Notice is hereby given that the staff of the Nuclear Regulatory Commission (NRC) has prepared a model safety evaluation (SE) relating to the impact of inoperable non-technical specification snubbers on supported systems in technical specifications (TS). The NRC staff has also prepared a model no-significant-hazards-consideration (NSHC) determination relating to this matter. The purpose of these models is to permit the NRC to efficiently process amendments that propose to add an LCO 3.0.8 that provides a delay time for entering a supported system TS when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed. Licensees of nuclear power reactors to which the models apply could then request amendments, confirming the applicability of the SE and NSHC determination to their reactors. The NRC staff is requesting comment on the model SE and model NSHC determination prior to announcing their availability for referencing in license amendment applications.

DATES: The comment period expires December 27, 2004. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Comments may be submitted either electronically or via U.S. mail. Submit written comments to Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T–6 D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Hand deliver comments to: 11545 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike (Room O–1F21), Rockville, Maryland. Comments may be submitted by electronic mail to *CLIIP@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Tom Boyce, Mail Stop: O–12H4, Division of Inspection Program Management, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone 301–415–0184.

SUPPLEMENTARY INFORMATION:

Background

Regulatory Issue Summary 2000–06, ''Consolidated Line Item Improvement Process for Adopting Standard Technical Specification Changes for Power Reactors,'' was issued on March 20, 2000. The consolidated line item improvement process (CLIIP) is intended to improve the efficiency of NRC licensing processes by processing proposed changes to the standard technical specifications (STS) in a manner that supports subsequent license amendment applications. The CLIIP includes an opportunity for the public to comment on a proposed change to the STS after a preliminary assessment by the NRC staff and a finding that the change will likely be offered for adoption by licensees. This notice solicits comment on a proposed change that allows a delay time for entering a supported system TS when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed. The CLIIP directs the NRC staff to evaluate any comments received for a proposed change to the STS and to either reconsider the change or announce the availability of the change for adoption by licensees. Licensees opting to apply for this TS change are responsible for reviewing the staff's evaluation, referencing the applicable technical justifications, and providing any necessary plant-specific information. Each amendment application made in response to the notice of availability will be processed and noticed in accordance with applicable rules and NRC procedures.

This notice involves the addition of LCO 3.0.8 to the TS which provides a delay time for entering a supported system TS when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed. This change was proposed for incorporation into the standard technical specifications by the owners groups participants in the Technical Specification Task Force (TSTF) and is designated TSTF–372. TSTF–372 can be viewed on the NRC's Web page at *http://www.nrc.gov/reactors/operating/licensing/techspecs.html.*

Applicability

This proposal to modify technical specification requirements by the

addition of LCO 3.0.8, as proposed in TSTF–372, is applicable to all licensees who have adopted or will adopt, in conjunction with the proposed change, technical specification requirements for a Bases control program consistent with the TS Bases Control Program described in Section 5.5 of the applicable vendor's STS.

To efficiently process the incoming license amendment applications, the staff requests that each licensee applying for the changes proposed in TSTF–372 include Bases for the proposed TS consistent with the Bases proposed in TSTF–372. In addition, licensees that have not adopted requirements for a Bases control program by converting to the improved STS or by other means are requested to include the requirements for a Bases control program consistent with the STS in their application for the proposed change. The need for a Bases control program stems from the need for adequate regulatory control of some key elements of the proposal that are contained in the proposed Bases for LCO 3.0.8. The staff is requesting that the Bases be included with the proposed license amendments in this case because the changes to the TS and the changes to the associated Bases form an integral change to a plant's licensing basis. To ensure that the overall change, including the Bases, includes appropriate regulatory controls, the staff plans to condition the issuance of each license amendment on the licensee's incorporation of the changes into the Bases document and on requiring the licensee to control the changes in accordance with the Bases Control Program. The CLIIP does not prevent licensees from requesting an alternative approach or proposing the changes without the requested Bases and Bases control program. However, deviations from the approach recommended in this notice may require additional review by the NRC staff and may increase the time and resources needed for the review.

Public Notices

This notice requests comments from interested members of the public within 30 days of the date of publication in the **Federal Register**. After evaluating the comments received as a result of this notice, the staff will either reconsider the proposed change or announce the availability of the change in a subsequent notice (perhaps with some changes to the safety evaluation or the proposed no significant hazards consideration determination as a result of public comments). If the staff announces the availability of the change, licensees wishing to adopt the change must submit an application in accordance with applicable rules and other regulatory requirements. For each application the staff will publish a notice of consideration of issuance of amendment to facility operating licenses, a proposed no significant hazards consideration determination, and a notice of opportunity for a hearing. The staff will also publish a notice of issuance of an amendment to an operating license to announce the modification of requirements for mode change limitations for each plant that receives the requested change.

Proposed Safety Evaluation

U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Consolidated Line Item Improvement, Technical Specification Task Force (TSTF) Change TSTF–372; The Addition of Limiting Condition for Operation (LCO) 3.0.8 on the Inoperability of Snubbers

1.0 Introduction

On April 23, 2004, the Nuclear Energy Institute (NEI) Risk Informed Technical Specifications Task Force (RITSTF) submitted a proposed change, TSTF–372, Revision 4, to the standard technical specifications (STS) (NUREGs 1430–1434) on behalf of the industry (TSTF–372, Revisions 1 through 3 were prior draft iterations). TSTF–372, Revision 4, is a proposal to add an STS Limiting Condition for Operation (LCO) 3.0.8, allowing a delay time for entering a supported system technical specification (TS), when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed. The postulated seismic event requiring snubbers is a low-probability occurrence and the overall TS system safety function would still be available for the vast majority of anticipated challenges.

This proposal is one of the industry's initiatives being developed under the risk-informed technical specifications program. These initiatives are intended to maintain or improve safety through the incorporation of risk assessment and management techniques in TS, while reducing unnecessary burden and making technical specification requirements consistent with the Commission's other risk-informed regulatory requirements, in particular the Maintenance Rule.

The proposed change adds a new limiting condition of operation, LCO 3.0.8, to the TS. LCO 3.0.8 allows licensees to delay declaring an LCO not met for equipment, supported by snubbers unable to perform their associated support functions, when risk is assessed and managed. This new LCO 3.0.8 states:

> When one or more required snubbers are unable to perform their associated support function(s), any affected supported LCO(s) are not required to be declared not met solely for this reason if risk is assessed and managed, and:
>
> a. The snubbers not able to perform their associated support function(s) are associated with only one train or subsystem of a multiple train or subsystem supported system or are associated with a single train or subsystem supported system and are able to perform their associated support function within 72 hours; or
>
> b. The snubbers not able to perform their associated support function(s) are associated with more than one train or subsystem of a multiple train or subsystem supported system and are able to perform their associated support function within 12 hours.
>
> At the end of the specified period the required snubbers must be able to perform their associated support function(s), or the affected supported system LCO(s) shall be declared not met.

2.0 Regulatory Evaluation

In 10 CFR 50.36, the Commission established its regulatory requirements related to the content of TS. Pursuant to 10 CFR 50.36, TS are required to include items in the following five specific categories related to station operation: (1) Safety limits, limiting safety system settings, and limiting control settings; (2) limiting conditions for operation (LCOs); (3) surveillance requirements (SRs); (4) design features; and (5) administrative controls. The rule does not specify the particular requirements to be included in a plant's TS. As stated in 10 CFR 50.36(c)(2)(i), the ''Limiting conditions for operation are the lowest functional capability or performance levels of equipment required for safe operation of the facility. When a limiting condition for operation of a nuclear reactor is not met, the licensee shall shut down the reactor or follow any remedial action permitted by the technical specification * * *.'' TS Section 3.0, on ''LCO and SR Applicability,'' provides details or ground rules for complying with the LCOs. Snubbers are chosen in lieu of rigid supports in areas where restricting thermal growth during normal operation would induce excessive stresses in the piping nozzles or other equipment. Although they are classified as component standard supports, they are not designed to provide any transmission of force during normal plant operations. However, in the presence of dynamic transient loadings, which are induced by seismic events as well as by plant accidents and transients, a snubber functions as a rigid support. The location and size of the

snubbers are determined by stress analysis based on different combinations of load conditions, depending on the design classification of the particular piping.

Prior to the conversion to the improved STS, TS requirements applied directly to snubbers. These requirements included:

- A requirement that snubbers be functional and in service when the supported equipment is required to be operable,
- A requirement that snubber removal for testing be done only during plant shutdown,
- A requirement that snubber removal for testing be done on a one-at-a-time basis when supported equipment is required to be operable during shutdown,
- A requirement to repair or replace within 72 hours any snubbers, found to be inoperable during operation in Modes 1 through 4, to avoid declaring any supported equipment inoperable,
- A requirement that each snubber be demonstrated operable by periodic visual inspections, and
- A requirement to perform functional tests on a representative sample of at least 10% of plant snubbers, at least once every 18 months during shutdown.

In the late 1980s, a joint initiative of the NRC and industry was undertaken to improve the STS. This effort identified the snubbers as candidates for relocation to a licensee-controlled document based on the fact that the TS requirements for snubbers did not meet any of the four criteria in 10 CFR 50.36(c)(2)(ii) for inclusion in the improved STS. The NRC approved the relocation without placing any restriction on the use of the relocated requirements. However, this relocation resulted in different interpretations between the NRC and the industry regarding its implementation. The NRC has stated, that since snubbers are supporting safety equipment that is in the TS, the definition of Operability must be used to immediately evaluate equipment supported by a removed snubber and, if found inoperable, the appropriate TS required actions must be entered. This interpretation has in practice eliminated the 72-hour delay to enter the actions for the supported equipment that existed prior to the conversion to the improved STS (the only exception is if the supported system has been analyzed and determined to be Operable without the snubber). The industry has argued that since the NRC approved the relocation without placing any restriction on the use of the relocated requirements, the licensee controlled document requirements for snubbers should be invoked before the supported system's TS requirements become applicable. The industry's interpretation would, in effect, restore the 72-hour delay to enter the actions for the supported equipment that existed prior to the conversion to the improved STS. However, prior to the conversion to the improved STS, the delay was applicable only to snubbers found to be inoperable (*i.e.*, to emergent conditions only). The industry's interpretation would allow a time delay for all conditions, including snubber removal for testing at power, that was not allowed prior to the conversion to the improved STS. The option to relocate the snubbers to a licensee controlled document, as part of the conversion to improved STS, has resulted in non-uniform and inconsistent treatment of snubbers. On the one hand, plants that have relocated snubbers from their TS are allowed to change the TS requirements for snubbers under the auspices of 10 CFR 50.59, but they are not allowed a 72-hour delay before they enter the actions for the supported equipment. On the other hand, plants that have not converted to improved STS have retained the 72-hour delay if snubbers are found to be inoperable, but they are not allowed to use 10 CFR 50.59 to change TS requirements for snubbers. It should also be noted that a few plants that converted to the improved STS chose not to relocate the snubbers to a licensee-controlled document and, thus, retained the 72-hour delay. In addition, it is important to note that unlike plants that have not relocated, plants that have relocated can perform functional tests on the snubbers at power (as long as they enter the actions for the supported equipment) and at the same time can reduce the testing frequency (as compared to plants that have not relocated) if it is justified by 10 CFR 50.59 assessments. Some potential undesirable consequences of this inconsistent treatment of snubbers are:

- Performance of testing during crowded time period windows when the supported system is inoperable with the potential to reduce the snubber testing to a minimum since the relocated snubber requirements are controlled by the licensee,
- Performance of testing during crowded windows when the supported system is inoperable with the potential to increase the unavailability of safety systems, and
- Performance of testing and maintenance on snubbers affecting multiple trains of the same supported system during the 7 hours allotted before entering MODE 3 under LCO 3.0.3.

To remove the inconsistency in the treatment of snubbers among plants, the TSTF proposed a risk-informed TS change that introduces a delay time before entering the actions for the supported equipment, when one or more snubbers are found inoperable or removed for testing, if risk is assessed and managed. Such a delay time will provide needed flexibility in the performance of maintenance and testing during power operation and at the same time will enhance overall plant safety by:

- Avoiding unnecessary unscheduled plant shutdowns and, thus, minimizing plant transition and realignment risks,
- Avoiding reduced snubber testing, and thus increasing the availability of snubbers to perform their supporting function,
- Performing most of the required testing and maintenance during the delay time when the supported system is available to mitigate most challenges and, thus, avoiding increases in safety system unavailability, and
- Providing explicit risk-informed guidance in areas in which that guidance currently does not exist, such as the treatment of snubbers impacting more than one redundant train of a supported system.

The proposed TS change is described in Sections 1.0 and 2.0. The technical evaluation and approach used to assess its risk impact is discussed in Section 3.0. The results and insights of the risk assessment are presented and discussed in Section 3.1. Section 3.2 summarizes the staff's conclusions from the review of the proposed TS change.

3.0 Technical Evaluation

The industry submitted TSTF–372, Revision 4, ''Addition of LCO 3.0.8, Inoperability of Snubbers'' in support of the proposed TS change. This submittal (Ref. 1) documents a risk-informed analysis of the proposed TS change. Probabilistic risk assessment (PRA) results and insights are used, in combination with deterministic and defense-in-depth arguments, to identify and justify delay times for entering the actions for the supported equipment associated with inoperable snubbers at nuclear power plants. This is in accordance with guidance provided in Regulatory Guides (RGs) 1.174 and 1.177 (Refs. 2 and 3, respectively).

The risk impact associated with the proposed delay times for entering the TS actions for the supported equipment can be assessed using the same approach as for allowed completion time (CT) extensions. Therefore, the risk

assessment was performed following the three-tiered approach recommended in RG 1.177 for evaluating proposed extensions in currently allowed CTs:

- The first tier involves the assessment of the change in plant risk due to the proposed TS change. Such risk change is expressed (1) by the change in the average yearly core damage frequency (ΔCDF) and the average yearly large early release frequency (ΔLERF) and (2) by the incremental conditional core damage probability (ICCDP) and the incremental conditional large early release probability (ICLERP). The assessed ΔCDF and ΔLERF values are compared to acceptance guidelines, consistent with the Commission's Safety Goal Policy Statement as documented in RG 1.174, so that the plant's average baseline risk is maintained within a minimal range. The assessed ICCDP and ICLERP values are compared to acceptance guidelines provided in RG 1.177, which aim at ensuring that the plant risk does not increase unacceptably during the period the equipment is taken out of service.
- The second tier involves the identification of potentially high-risk configurations that could exist if equipment in addition to that associated with the change were to be taken out of service simultaneously, or other risk-significant operational factors such as concurrent equipment testing were also involved. The objective is to ensure that appropriate restrictions are in place to avoid any potential high-risk configurations.
- The third tier involves the establishment of an overall configuration risk management program (CRMP) to ensure that potentially risk-significant configurations resulting from maintenance and other operational activities are identified. The objective of the CRMP is to manage configuration-specific risk by appropriate scheduling of plant activities and/or appropriate compensatory measures.

A simplified bounding risk assessment was performed to justify the proposed addition of LCO 3.0.8 to the TS. This approach was necessitated by (1) the general nature of the proposed TS changes (*i.e.*, they apply to all plants and are associated with an undetermined number of snubbers that are not able to perform their function), (2) the lack of detailed engineering analyses that establish the relationship between earthquake level and supported system pipe failure probability when one or more snubbers are inoperable, and (3) the lack of seismic risk assessment models for most plants. The simplified risk assessment is based on the following major assumptions, which the staff finds acceptable, as discussed below:

- The accident sequences contributing to the risk increase associated with the proposed TS changes are assumed to be initiated by a seismically-induced loss-of-offsite-power (LOOP) event with concurrent loss of all safety system trains supported by the out-of-service snubbers. In the case of snubbers associated with more than one train (or subsystem) of the same system, it is assumed that all affected trains (or subsystems) of the supported system are failed. This assumption was introduced to allow the performance of a simple bounding risk assessment approach with application to all plants. This approach was selected due to the lack of detailed plant-specific seismic risk assessments for most plants and the lack of fragility data for piping when one or more supporting snubbers are inoperable.
- The LOOP event is assumed to occur due to the seismically-induced failure of the ceramic insulators used in the power distribution systems. These ceramic insulators have a high confidence (95%) of low probability (5%) of failure (HCLPF) of about 0.1g, expressed in terms of peak ground acceleration. Thus, a magnitude 0.1g earthquake is conservatively assumed to have 5% probability of causing a LOOP initiating event. The fact that no LOOP events caused by higher magnitude earthquakes were considered is justified because (1) the frequency of earthquakes decreases with increasing magnitude and (2) historical data (References 4 and 5) indicate that the mean seismic capacity of ceramic insulators (used in seismic PRAs), in terms of peak ground acceleration, is about 0.3g, which is significantly higher than the 0.1g HCLPF value. Therefore, the simplified analysis, even though it does not consider LOOP events caused by earthquakes of magnitude higher than 0.1g, bounds a detailed analysis which would use mean seismic failure probabilities (fragilities) for the ceramic insulators.
- Analytical and experimental results obtained in the mid-eighties as part of the industry's ''Snubber Reduction Program'' (References 4 and 6) indicated that piping systems have large margins against seismic stress. The assumption that a magnitude 0.1g earthquake would cause the failure of all safety system trains supported by the out-of-service snubbers is very conservative because safety piping systems could withstand much higher seismic stresses even when one or more supporting snubbers are out of service. The actual piping failure probability is a function of the stress allowable and the number of snubbers removed for maintenance or testing. Since the licensee controlled testing is done on only a small (about 10%) representative sample of the total snubber population, it is not expected to have more than a few snubbers supporting a given safety system out for testing at a time. Furthermore, since the testing of snubbers is a planned activity, licensees have flexibility in selecting a sample set of snubbers for testing from a much larger population by conducting configuration-specific engineering and/or risk assessments. Such a selection of snubbers for testing provides confidence that the supported systems would perform their functions in the presence of a design-basis earthquake and other dynamic loads and, in any case, the risk impact of the activity will remain within the limits of acceptability defined in risk-informed RGs 1.174 and 1.177.
- The analysis assumes that one train (or subsystem) of all safety systems is unavailable during snubber testing or maintenance (an entire system is assumed unavailable if a removed snubber is associated with both trains of a two-train system). This is a very conservative assumption for the case of corrective maintenance since it is unlikely that a visual inspection will reveal that one or more snubbers across all supported systems are inoperable. This assumption is also conservative for the case of the licensee-controlled testing of snubbers since such testing is performed only on a small representative sample.
- In general, no credit is taken for recovery actions and alternative means of performing a function, such as the function performed by a system assumed failed (*e.g.*, when LCO 3.0.8b applies). However, most plants have reliable alternative means of performing certain critical functions. For example, feed and bleed (F&B) can be used to remove heat in most pressurized water reactors (PWRs) when auxiliary feedwater (AFW), the most important system in mitigating LOOP accidents, is unavailable. Similarly, if high pressure makeup (*e.g.*, reactor core isolation cooling) and heat removal capability (*e.g.*, suppression pool cooling) are unavailable in boiling water reactors (BWRs), reactor depressurization in conjunction with low pressure makeup (*e.g.*, low pressure coolant injection) and heat removal capability (*e.g.*, shutdown cooling) can be used to cool the core. A 10% failure probability for recovery actions to provide core cooling using alternative means is assumed for Diablo Canyon, the only West Coast PWR plant

with F&B capability, when a snubber impacting more than one train of the AFW system (*i.e.*, when LCO 3.0.8b is applicable) is out of service. This failure probability value is significantly higher than the value of 2.2E–2 used in Diablo Canyon's PRA. Furthermore, Diablo Canyon has analyzed the impact of a single limiting snubber failure, and concluded that no single snubber failure would impact two trains of AFW. No credit for recovery actions to provide core cooling using alternative means is necessary for West Coast PWR plants with no F&B capability because it has been determined that there is no single snubber whose non-functionality would disable two trains of AFW in a seismic event of magnitude up to the plant's safe shutdown earthquake (SSE). It should be noted that a similar credit could have been applied to most Central and Eastern U.S. plants but this was not necessary to demonstrate the low risk impact of the proposed TS change due to the lower earthquake frequencies at Central and Eastern U.S. plants as compared to West Coast plants.

- The earthquake frequency at the 0.1g level was assumed to be 1E–3/year for Central and Eastern U.S. plants and 1E–1/year for West Coast plants. Each of these two values envelop the range of earthquake frequency values at the 0.1g level, for Eastern U.S. and West Coast sites, respectively (References 5 and 7).
- The risk impact associated with non-LOOP accident sequences (*e.g.*, seismically initiated loss-of-coolant-accident (LOCA) or anticipated-transient-without-scram (ATWS) sequences) was not assessed. However, this risk impact is small compared to the risk impact associated with the LOOP accident sequences modeled in the simplified bounding risk assessment. Non-LOOP accident sequences, due to the ruggedness of nuclear power plant designs, require seismically-induced failures that occur at earthquake levels above 0.3g. Thus, the frequency of earthquakes initiating non-LOOP accident sequences is much smaller than the frequency of seismically-initiated LOOP events. Furthermore, because of the conservative assumption made for LOOP sequences that a 0.1g level earthquake would fail all piping associated with inoperable snubbers, non-LOOP sequences would not include any more failures associated with inoperable snubbers than LOOP sequences. Therefore, the risk impact of inoperable snubbers associated with non-LOOP accident sequences is small compared to the risk impact associated with the LOOP accident sequences modeled in the simplified bounding risk assessment.
- The risk impact of dynamic loadings other than seismic loads is not assessed. These shock-type loads include thrust loads, blowdown loads, waterhammer loads, steamhammer loads, LOCA loads and pipe rupture loads. However, there are some important distinctions between non-seismic (shock-type) loads and seismic loads which indicate that, in general, the risk impact of the out-of-service snubbers is smaller for non-seismic loads than for seismic loads. First, while a seismic load affects the entire plant, the impact of a non-seismic load is localized to a certain system or area of the plant. Second, although non-seismic shock loads may be higher in total force and the impact could be as much or more than seismic loads, generally they are of much shorter duration than seismic loads. Third, the impact of non-seismic loads is more plant specific, and thus harder to analyze generically, than for seismic loads. For these reasons, licensees will be required to perform an engineering assessment every time LCO 3.0.8 is used and show that at least one train of each system that is supported by the inoperable snubber(s) would remain capable of performing their required safety or support functions for postulated design loads other than seismic loads.

3.1 Risk Assessment Results and Insights

The results and insights from the implementation of the three-tiered approach of RG 1.177 to support the proposed addition of LCO 3.0.8 to the TS are summarized and evaluated in the following sections 3.1.1 to 3.1.3.

3.1.1 Risk Impact

The bounding risk assessment approach, discussed in section 3.0, was implemented generically for all U.S. operating nuclear power plants. Risk assessments were performed for two categories of plants, Central and East Coast plants and West Coast plants, based on historical seismic hazard curves (earthquake frequencies and associated magnitudes). The first category, Central and East Coast plants, includes the vast majority of the U.S. nuclear power plant population (Reference 7). For each category of plants, two risk assessments were performed:

- The first risk assessment applies to cases where all inoperable snubbers are associated with only one train (or subsystem) of the impacted safety systems. It was conservatively assumed that a single train (or subsystem) of each safety system is unavailable. It was also assumed that the probability of non-mitigation using the unaffected redundant trains (or subsystems) is 2%. This is a conservative value given that for core damage to occur under those conditions, two or more failures are required.
- The second risk assessment applies to the case where one or more of the inoperable snubbers are associated with multiple trains (or subsystems) of the same safety systems. It was assumed in this bounding analysis that all safety systems are unavailable to mitigate the accident, except for West Coast PWR plants. Credit for using F&B to provide core cooling is taken for plants having F&B capability (*e.g.*, Diablo Canyon) when a snubber impacting more than one train of the AFW system is inoperable. Credit for one AFW train to provide core cooling is taken for West Coast PWR plants with no F&B capability (*e.g.*, San Onofre) because it has been determined that there is no single snubber whose non-functionality would disable two trains of AFW in a seismic event of magnitude up to the plant's safe shutdown earthquake (SSE).

The results of the performed risk assessments, in terms of core damage and large early release risk impacts, are summarized in Table 1. The first row lists the conditional risk increase, in terms of CDF (core damage frequency), $\Delta R_{CDF,}$ caused by the out-of-service snubbers (as assumed in the bounding analysis). The second and third rows list the ICCDP (incremental conditional core damage probability) and the ICLERP (incremental conditional large early release probability) values, respectively. The ICCDP for the case where all inoperable snubbers are associated with only one train (or subsystem) of the supported safety systems, was obtained by multiplying the corresponding ΔR_{CDF} value by the time fraction of the proposed 72-hour delay to enter the actions for the supported equipment. The ICCDP for the case where one or more of the inoperable snubbers are associated with multiple trains (or subsystems) of the same safety system, was obtained by multiplying the corresponding ΔR_{CDF} value by the time fraction of the proposed 12-hour delay to enter the actions for the supported equipment. The ICLERP values were obtained by multiplying the corresponding ICCDP values by 0.1 (*i.e.*, by assuming that the ICLERP value is an order of magnitude less than the ICCDP). This assumption is conservative since containment bypass scenarios, such as steam generator tube rupture accidents and interfacing system loss-of-coolant accidents, would not be

uniquely affected by the out-of-service snubbers. Finally, the fourth and fifth rows list the assessed ΔCDF and ΔLERF values, respectively. These values were obtained by dividing the corresponding ICCDP and ICLERP values by 1.5 (*i.e.*, by assuming that the snubbers are tested every 18 months, as was the case before the snubbers were relocated to a licensee-controlled document). This assumption is reasonable because (1) it is not expected that licensees would test the snubbers more often than what used to be required by the TS, and (2) testing of snubbers is associated with higher risk impact than the average corrective maintenance of snubbers found inoperable by visual inspection (testing is expected to involve significantly more snubbers out of service than corrective maintenance). The assessed ΔCDF and ΔLERF values are compared to acceptance guidelines, consistent with the Commission's Safety Goal Policy Statement as documented in RG 1.174, so that the plant's average baseline risk is maintained within a minimal range. This comparison indicates that the addition of LCO 3.0.8 to the existing TS would have an insignificant risk impact.

TABLE 1.—BOUNDING RISK ASSESSMENT RESULTS FOR SNUBBERS IMPACTING A SINGLE TRAIN AND MULTIPLE TRAINS OF A SUPPORTED SYSTEM

	Central and east coast plants		West coast plants	
	Single train	Multiple train	Single train	Multiple train
ΔR_{CDF}/yr	1E–6	5E–6	1E–4	5E–4
ICCDP	8E–9	7E–9	8E–7	7E–7
ICLERP	8E–10	7E–10	8E–8	7E–8
ΔCDF/yr	5E–9	5E–9	5E–7	5E–7
ΔLERF/yr	5E–10	5E–10	5E–8	5E–8

The assessed ΔCDF and ΔLERF values meet the acceptance criteria of 1E–6/year and 1E–7/year, respectively, based on guidance provided in RG 1.174. This conclusion is true without taking any credit for the removal of potential undesirable consequences associated with the current inconsistent treatment of snubbers (*e.g.*, reduced snubber testing frequency, increased safety system unavailability and treatment of snubbers impacting multiple trains) discussed in Section 1 above, and given the bounding nature of the risk assessment.

The assessed ICCDP and ICLERP values are compared to acceptance guidelines provided in RG 1.177, which aim at ensuring that the plant risk does not increase unacceptably during the period the equipment is taken out of service. This comparison indicates that the addition of LCO 3.0.8 to the existing TS meets the RG 1.177 numerical guidelines of 5E–7 for ICCDP and 5E–8 for ICLERP. The small deviations shown for West Coast plants are acceptable because of the bounding nature of the risk assessments, as discussed in section 2.

The risk assessment results of Table 1 are also compared to guidance provided in the revised section 11 of NUMARC 93–01, Revision 2 (Reference 8), endorsed by RG 1.182 (Reference 9), for implementing the requirements of paragraph (a)(4) of the Maintenance Rule, 10 CFR 50.65. Such guidance is summarized in Table 2. Guidance regarding the acceptability of conditional risk increase in terms of CDF (*i.e.*, ΔR_{CDF}) for a planned configuration is provided. This guidance states that a specific configuration that is associated with a CDF higher than 1E–3/year should not be entered voluntarily. Since the assessed conditional risk increase, ΔR_{CDF}, is significantly less than 1E–3/year, plant configurations including out of service snubbers and other equipment may be entered voluntarily if supported by the results of the risk assessment required by 10 CFR 50.65(a)(4), by LCO 3.0.8, or by other TS.

TABLE 2.—GUIDANCE FOR IMPLEMENTING 10 CFR 50.65(a)(4)

ΔR_{CDF}	Guidance
Greater than 1E–3/year	Configuration should not normally be entered voluntarily.

ICCDP	Guidance	ICLERP
Greater than 1E–5	Configuration should not normally be entered voluntarily	Greater than 1E–6.
1E–6 to 1E–5	Assess non-quantifiable factors Establish risk management actions.	1E–7 to 1E–6.
Less than 1E–6	Normal work controls	Less than 1E–7.

Guidance regarding the acceptability of ICCDP and ICLERP values for a specific planned configuration and the establishment of risk management actions is also provided in NUMARC 93–01. This guidance, as shown in Table 2, states that a specific plant configuration that is associated with ICCDP and ICLERP values below 1E–6 and 1E–7, respectively, is considered to require ''normal work controls.'' Table 1 shows that for the majority of plants (*i.e.*, for all plants in the Central and East Coast category) the conservatively assessed ICCDP and ICLERP values are over an order of magnitude less than what is recommended as the threshold for the ''normal work controls'' region. For West Coast plants, the conservatively assessed ICCDP and ICLERP values are still within the ''normal work controls'' region. Thus, the risk contribution from out of service snubbers is within the normal range of maintenance activities carried out at a plant. Therefore, plant configurations involving out of service snubbers and other equipment may be entered voluntarily if supported by the results of the risk assessment required by 10 CFR

50.65(a)(4), by LCO 3.0.8, or by other TS. However, this simplified bounding analysis indicates that for West Coast plants the provisions of LCO 3.0.8 must be used cautiously and in conjunction with appropriate management actions, especially when equipment other than snubbers is also inoperable, based on the results of configuration-specific risk assessments required by 10 CFR 50.65(a)(4), by LCO 3.0.8, or by other TS.

The staff finds that the risk assessment results support the proposed addition of LCO 3.0.8 to the TS. The risk increases associated with this TS change will be insignificant based on guidance provided in RGs 1.174 and 1.177 and within the range of risks associated with normal maintenance activities. In addition, LCO 3.0.8 will remove potential undesirable consequences stemming from the current inconsistent treatment of snubbers in the TS, such as reduced frequency of snubber testing, increased safety system unavailability and the treatment of snubbers impacting multiple trains.

3.1.2 Identification of High-Risk Configurations

The second tier of the three-tiered approach recommended in RG 1.177 involves the identification of potentially high-risk configurations that could exist if equipment, in addition to that associated with the TS change, were to be taken out of service simultaneously. Insights from the risk assessments, in conjunction with important assumptions made in the analysis and defense-in-depth considerations, were used to identify such configurations. To avoid these potentially high-risk configurations, specific restrictions to the implementation of the proposed TS changes were identified.

For cases where all inoperable snubbers are associated with only one train (or subsystem) of the impacted systems (*i.e.*, when LCO 3.0.8a applies), it was assumed in the analysis that there will be unaffected redundant trains (or subsystems) available to mitigate the seismically initiated LOOP accident sequences. This assumption implies that there will be at least one success path available when LCO 3.0.8a applies. Therefore, potentially high-risk configurations can be avoided by ensuring that such a success path exists when LCO 3.0.8a applies. Based on a review of the accident sequences that contribute to the risk increase associated with LCO 3.0.8a, as modeled by the simplified bounding analysis (*i.e.*, accident sequences initiated by a seismically-induced LOOP event with concurrent loss of all safety system trains supported by the out of service snubbers), the following restrictions were identified to prevent potentially high-risk configurations:

- For PWR plants, at least one AFW train (including a minimum set of supporting equipment required for its successful operation) not associated with the inoperable snubber(s), must be available when LCO 3.0.8a is used
- For BWR plants, one of the following two means of heat removal must be available when LCO 3.0.8a is used:

—At least one high pressure makeup path (*e.g.*, using high pressure coolant injection (HPCI) or reactor core isolation cooling (RCIC) or equivalent) and heat removal capability (*e.g.*, suppression pool cooling), including a minimum set of supporting equipment required for success, not associated with the inoperable snubber(s), or

—At least one low pressure makeup path (*e.g.*, low pressure coolant injection (LPCI) or containment spray (CS)) and heat removal capability (*e.g.*, suppression pool cooling or shutdown cooling), including a minimum set of supporting equipment required for success, not associated with the inoperable snubber(s).

For cases where one or more of the inoperable snubbers are associated with multiple trains (or subsystems) of the same safety system (*i.e.*, when LCO 3.0.8b applies), it was assumed in the bounding analysis that all safety systems are unavailable to mitigate the accident, except for West Coast plants. Credit for using F&B to provide core cooling is taken for plants having F&B capability (*e.g.*, Diablo Canyon) when a snubber impacting more than one train of the AFW system is inoperable. Credit for one AFW train to provide core cooling is taken for West Coast PWR plants with no F&B capability (*e.g.*, San Onofre) because it has been determined that there is no single snubber whose non-functionality would disable more than one train of AFW in a seismic event of magnitude up to the plant's safe shutdown earthquake (SSE). Based on a review of the accident sequences that contribute to the risk increase associated with LCO 3.0.8b (as modeled by the simplified bounding analysis) and defense-in-depth considerations, the following restrictions were identified to prevent potentially high-risk configurations:

- LCO 3.0.8b cannot be used at West Coast PWR plants with no F&B capability when a snubber whose non-functionality would disable more than one train of AFW in a seismic event of magnitude up to the plant's safe shutdown earthquake (SSE) is inoperable (it should be noted, however, that based on information provided by the industry, there is no plant that falls in this category).
- When LCO 3.0.8b is used at PWR plants, at least one AFW train (including a minimum set of supporting equipment required for its successful operation) not associated with the inoperable snubber(s), or some alternative means of core cooling (*e.g.*, F&B, fire water system or ''aggressive secondary cooldown'' using the steam generators) must be available.
- When LCO 3.0.8b is used at BWR plants, it must be verified that at least one success path exists, using equipment not associated with the inoperable snubber(s), to provide makeup and core cooling needed to mitigate LOOP accident sequences.

3.1.3 Configuration Risk Management

The third tier of the three-tiered approach recommended in RG 1.177 involves the establishment of an overall configuration risk management program (CRMP) to ensure that potentially risk-significant configurations resulting from maintenance and other operational activities are identified. The objective of the CRMP is to manage configuration-specific risk by appropriate scheduling of plant activities and/or appropriate compensatory measures. This objective is met by licensee programs to comply with the requirements of paragraph (a)(4) of the Maintenance Rule (10 CFR 50.65) to assess and manage risk resulting from maintenance activities, and by the TS requiring risk assessments and management using (a)(4) processes if no maintenance is in progress. These programs can support licensee decision making regarding the appropriate actions to manage risk whenever a risk-informed TS is entered. Since the 10 CFR 50.65(a)(4) guidance, section 11 of NUMARC 93–01, does not currently address seismic risk, implementation guidance must be developed by licensees adopting this change to ensure that the proposed LCO 3.0.8 is considered with respect to other plant maintenance activities and integrated into the existing 10 CFR 50.65(a)(4) process whether the process is invoked by a TS or (a)(4) itself.

3.2 Summary and Conclusions

The option to relocate the snubbers to a licensee controlled document, as part of the conversion to Improved STS, has resulted in non-uniform and inconsistent treatment of snubbers. Some potential undesirable

consequences of this inconsistent treatment of snubbers are:

- Performance of testing during crowded windows when the supported system is inoperable with the potential to reduce the snubber testing to a minimum since the relocated snubber requirements are controlled by the licensee.
- Performance of testing during crowded windows when the supported system is inoperable with the potential to increase the unavailability of safety systems.
- Performance of testing and maintenance on snubbers affecting multiple trains of the same supported system during the 7 hours allotted before entering MODE 3 under limiting condition of operation (LCO) 3.0.3.

To remove the inconsistency among plants in the treatment of snubbers, licensees are proposing a risk-informed TS change which introduces a delay time before entering the actions for the supported equipment when one or more snubbers are found inoperable or removed for testing. Such a delay time will provide needed flexibility in the performance of maintenance and testing during power operation and at the same time will enhance overall plant safety by (1) avoiding unnecessary unscheduled plant shutdowns, thus, minimizing plant transition and realignment risks; (2) avoiding reduced snubber testing, thus, increasing the availability of snubbers to perform their supporting function; (3) performing most of the required testing and maintenance during the delay time when the supported system is available to mitigate most challenges, thus, avoiding increases in safety system unavailability; and (4) providing explicit risk-informed guidance in areas in which that guidance currently does not exist, such as the treatment of snubbers impacting more than one redundant train of a supported system.

The risk impact of the proposed TS changes was assessed following the three-tiered approach recommended in RG 1.177. A simplified bounding risk assessment was performed to justify the proposed TS changes. This bounding assessment assumes that the risk increase associated with the proposed addition of LCO 3.0.8 to the TS is associated with accident sequences initiated by a seismically-induced LOOP event with concurrent loss of all safety system trains supported by the out of service snubbers. In the case of snubbers associated with more than one train, it is assumed that all affected trains of the supported system are failed. This assumption was introduced to allow the performance of a simple bounding risk assessment approach with application to all plants and was selected due to the lack of detailed plant-specific seismic risk assessments for most plants and the lack of fragility data for piping when one or more supporting snubbers are inoperable. The impact from the addition of the proposed LCO 3.0.8 to the TS on defense-in-depth was also evaluated in conjunction with the risk assessment results.

Based on this integrated evaluation, the staff concludes that the proposed addition of LCO 3.0.8 to the TS would lead to insignificant risk increases, if any. Indeed, this conclusion is true without taking any credit for the removal of potential undesirable consequences associated with the current inconsistent treatment of snubbers, such as the effects of avoiding a potential reduction in the snubber testing frequency and increased safety system unavailability. To be consistent with the staff's approval, licensees interested in implementing LCO 3.0.8 must, as applicable, operate in accordance with the following stipulations:

1. Appropriate plant procedures and administrative controls will be used to implement the following Tier 2 Restrictions.

(a) At least one AFW train (including a minimum set of supporting equipment required for its successful operation) not associated with the inoperable snubber(s), must be available when LCO 3.0.8a is used at PWR plants.

(b) At least one AFW train (including a minimum set of supporting equipment required for its successful operation) not associated with the inoperable snubber(s), or some alternative means of core cooling (*e.g.*, F&B, fire water system or ''aggressive secondary cooldown'' using the steam generators) must be available when LCO 3.0.8b is used at PWR plants.

(c) LCO 3.0.8b cannot be used by West Coast PWR plants with no F&B capability when a snubber, whose non-functionality would disable more than one train of AFW in a seismic event of magnitude up to the plant's safe shutdown earthquake (SSE), is inoperable.

(d) BWR plants must verify, every time the provisions of LCO 3.0.8 are used, that at least one success path, involving equipment not associated with the inoperable snubber(s), exists to provide makeup and core cooling.

(e) Every time the provisions of LCO 3.0.8 are used licensees will be required to perform a risk assessment, and an operability assessment to show that at least one train (or subsystem) of systems supported by the inoperable snubbers would remain capable of performing their required safety or support functions for postulated design loads other than seismic loads. The operability assessment, consistent with the plants licensing design basis, must be documented and available for inspection by the staff.

2. Should licensees implement the provisions of LCO 3.0.8 for snubbers, which include delay times to enter the actions for the supported equipment when one or more snubbers are out of service for maintenance or testing, it must be done in accordance with an overall configuration risk management program (CRMP) to ensure that potentially risk-significant configurations resulting from maintenance and other operational activities are identified and avoided, as discussed in the proposed TS Bases. This objective is met by licensee programs to comply with the requirements of paragraph (a)(4) of the Maintenance Rule, 10 CFR 50.65, to assess and manage risk resulting from maintenance activities or when this process is invoked by LCO 3.0.8 or other TS. These programs can support licensee decision making regarding the appropriate actions to manage risk whenever a risk-informed TS is entered. Since the 10 CFR 50.65 (a)(4) guidance, Section 11 of NUMARC 93–01, does not currently address seismic risk, implementation guidance must be developed by licensees adopting this change to ensure that the proposed LCO 3.0.8 is considered in conjunction with other plant maintenance activities and integrated into the existing 10 CFR 50.65 (a)(4) process.

4.0 State Consultation

In accordance with the Commission's regulations, the [ ] State official was notified of the proposed issuance of the amendment. The State official had [(1) no comments or (2) the following comments—with subsequent disposition by the staff].

5.0 Environmental Consideration

The amendments change a requirement with respect to the installation or use of a facility component located within the restricted area as defined in 10 CFR part 20 and change surveillance requirements. [For licensees adding a Bases Control Program: The amendment also changes record keeping, reporting, or administrative procedures or requirements.] The NRC staff has determined that the amendments involve no significant increase in the amounts and no significant change in the types of any effluents that may be

released offsite, and that there is no significant increase in individual or cumulative occupational radiation exposure. The Commission has previously issued a proposed finding that the amendments involve no-significant-hazards considerations, and there has been no public comment on the finding [FR]. Accordingly, the amendments meet the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9) [and (c)(10)]. Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendments.

6.0 Conclusion

The Commission has concluded, on the basis of the considerations discussed above, that (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendments will not be inimical to the common defense and security or to the health and safety of the public.

7.0 References

1. TSTF–372, Revision 4, ''Addition of LCO 3.0.8, Inoperability of Snubbers,'' April 23, 2004.
2. Regulatory Guide 1.174, ''An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decision Making on Plant Specific Changes to the Licensing Basis,'' USNRC, August 1998.
3. Regulatory Guide 1.177, ''An Approach for Plant Specific Risk-Informed Decision Making: Technical Specifications,'' USNRC, August 1998.
4. Budnitz, R. J. *et al.*, ''An Approach to the Quantification of Seismic Margins in Nuclear Power Plants,'' NUREG/CR–4334, Lawrence Livermore National Laboratory, July 1985.
5. Advanced Light Water Reactor Utility Requirements Document, Volume 2, ALWR Evolutionary Plant, PRA Key Assumptions and Groundrules, Electric Power Research Institute, August 1990.
6. Bier V. M. *et al.*, ''Development and Application of a Comprehensive Framework for Assessing Alternative Approaches to Snubber Reduction,'' International Topical Conference on Probabilistic Safety Assessment and Risk Management PSA '87, Swiss Federal Institute of Technology, Zurich, August 30-September 4, 1987.
7. NUREG–1488, ''Revised Livermore Seismic Hazard Estimates for Sixty-Nine Nuclear Power Plant Sites East of the Rocky Mountains,'' April 1994.
8. NEI, Revised Section 11 of Revision 2 of NUMARC 93–01, May 2000.
9. Regulatory Guide 1.182, ''Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants,'' May 2000.

Proposed No-Significant-Hazards-Consideration Determination

Description of Amendment Request: A change is proposed to the standard technical specifications (STS)(NUREGs 1430 through 1434) and plant specific technical specifications (TS), to allow a delay time for entering a supported system technical specification (TS) when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed consistent with the program in place for complying with the requirements of 10 CFR 50.65(a)(4). LCO 3.0.8 will be added to individual TS providing this allowance.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change allows a delay time for entering a supported system technical specification (TS) when the inoperability is due solely to an inoperable snubber if risk is assessed and managed. The postulated seismic event requiring snubbers is a low-probability occurrence and the overall TS system safety function would still be available for the vast majority of anticipated challenges. Therefore, the probability of an accident previously evaluated is not significantly increased, if at all. The consequences of an accident while relying on allowance provided by proposed LCO 3.0.8 are no different than the consequences of an accident while relying on the TS required actions in effect without the allowance provided by proposed LCO 3.0.8. Therefore, the consequences of an accident previously evaluated are not significantly affected by this change. The addition of a requirement to assess and manage the risk introduced by this change will further minimize possible concerns. Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Previously Evaluated

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed). Allowing delay times for entering supported system TS when inoperability is due solely to inoperable snubbers, if risk is assessed and managed, will not introduce new failure modes or effects and will not, in the absence of other unrelated failures, lead to an accident whose consequences exceed the consequences of accidents previously evaluated. The addition of a requirement to assess and manage the risk introduced by this change will further minimize possible concerns. Thus, this change does not create the possibility of a new or different kind of accident from an accident previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The proposed change allows a delay time for entering a supported system TS when the inoperability is due solely to an inoperable snubber, if risk is assessed and managed. The postulated seismic event requiring snubbers is a low-probability occurrence and the overall TS system safety function would still be available for the vast majority of anticipated challenges. The risk impact of the proposed TS changes was assessed following the three-tiered approach recommended in RG 1.177. A bounding risk assessment was performed to justify the proposed TS changes. This application of LCO 3.0.8 is predicated upon the licensee's performance of a risk assessment and the management of plant risk. The net change to the margin of safety is insignificant. Therefore, this change does not involve a significant reduction in a margin of safety.

Based upon the reasoning presented above and the previous discussion of the amendment request, the requested change does not involve a no-significant-hazards consideration.

Dated at Rockville, Maryland, this 18th day of November, 2004.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Section Chief, Technical Specifications Section, Operating Improvements Branch, Division of Inspection Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 04–26008 Filed 11–23–04; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collections for OMB Review; Comment Request; Payment of Premiums; Filing, Issuance, Computation of Time, and Record Retention

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intention to request OMB approval of revision of collections of information.

SUMMARY: The Pension Benefit Guaranty Corporation (''PBGC'') intends to request Office of Management and Budget (''OMB'') approval, under the Paperwork Reduction Act, of revisions of the collections of information under its regulations on Payment of Premiums (29 CFR part 4007) (OMB control number 1212–0009; expires November 30, 2006) and on Filing, Issuance, Computation of Time, and Record Retention (29 CFR part 4000) (OMB control number 1212–0059; expires October 31, 2006). Collection of information 1212–0009 also includes a certification of compliance with requirements to provide certain notices to participants under the PBGC's regulation on Disclosure to Participants (29 CFR part 4011). The PBGC is revising the collections of information to provide for an alternative means of electronic filing of premium information, in addition to the PBGC's existing e-filing method using ''My Plan Administration Account'' (''My PAA'') through the PBGC's Web site. The alternative e-filing method is being developed in connection with an anticipated PBGC proposal to require electronic premium filing in the near future. This notice informs the public of the PBGC's intent and solicits public comment on the collections of information.

DATES: Comments should be submitted by January 24, 2005.

ADDRESSES: Comments may be mailed to the Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, or delivered to Suite 340 at that address during normal business hours. Comments also may be submitted electronically through the PBGC's Web site at *http://www.pbgc.gov/paperwork*, or by fax to 202–326–4112. The PBGC will make all comments available on its Web site at *http://www.pbgc.gov*.

Copies of the collections of information may be obtained without charge by writing to the PBGC's Communications and Public Affairs Department at Suite 240 at the above address or by visiting that office or calling 202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.) The premium payment, participant notice, and filing regulations and the paper premium forms and instructions for 2004 and prior years can be accessed on the PBGC's Web site at *http://www.pbgc.gov;* the My PAA forms and instructions can also be accessed through the Web site by My PAA users.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy, Staff Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, 202–326–4024. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: Section 4007 of Title IV of the Employee Retirement Income Security Act of 1974 (''ERISA'') requires the Pension Benefit Guaranty Corporation (''PBGC'') to collect premiums from pension plans covered under Title IV pension insurance programs. Pursuant to ERISA section 4007, the PBGC has issued its regulation on Payment of Premiums (29 CFR part 4007). Section 4007.3 of the premium payment regulation requires plans, in connection with the payment of premiums, to file forms prescribed by the PBGC and refers filers to subpart A of its regulation on Filing, Issuance, Computation of Time, and Record Retention (29 CFR part 4000) for rules on permissible filing methods. Section 4007.10 of the premium payment regulation requires plans to retain and make available to the PBGC records supporting or validating the computation of premiums paid. Subpart A of part 4000 states the methods that may be used for sending a filing to the PBGC. (Payments are treated as filings.)

The PBGC has prescribed a series of paper premium forms: Form 1–ES, Form 1–EZ, and Form 1 and (for single-employer plans only) Schedule A to Form 1. Form 1–ES is issued, with instructions, in the PBGC's Estimated Premium Payment Package. Form 1–EZ, Form 1, and Schedule A are issued, with instructions, in the PBGC's Annual Premium Payment Package. In addition, the PBGC provides for premium filing through an electronic facility, ''My Plan Administration Account'' (''MyPAA''), on its Web site at *http://www.pbgc.gov*. The forms that filers prepare using My PAA are not in the same format as the paper premium forms, but they solicit the same premium information.

Premium forms are used to report the computation, determine the amount, and record the payment of PBGC premiums. The submission of premium information and retention and submission of premium records are needed to enable the PBGC to perform premium audits. The plan administrator of each pension plan covered by Title IV of ERISA is required to file one or more premium forms each year. The PBGC uses the information on the premium forms to identify the plans paying premiums; to verify whether plans are paying the correct amounts; and to help the PBGC determine the magnitude of its exposure in the event of plan termination. That information and the retained records are used for audit purposes.

In addition, section 4011 of ERISA and the PBGC's regulation on Disclosure to Participants (29 CFR part 4011) require plan administrators of certain underfunded single-employer pension plans to provide an annual notice to plan participants and beneficiaries of the plans' funding status and the limits on the PBGC's guarantee of plan benefits. In general, the participant notice requirement applies (subject to certain exemptions) to plans that must pay a variable-rate premium. In order to monitor compliance with part 4011, single-employer plan administrators must indicate in their premium filings whether the participant notice requirements have been complied with.

The collection of information under the regulation on Payment of Premiums, including Form 1–ES, Form 1–EZ, Form 1, and Schedule A to Form 1, corresponding My PAA electronic forms, and related instructions has been approved by the Office of Management and Budget (''OMB'') under control number 1212–0009. The collection of information also includes the certification of compliance with the participant notice requirements (but not the participant notices themselves).

The collection of information under the regulation on Filing, Issuance, Computation of Time, and Record Retention has been approved by the Office of Management and Budget (''OMB'') under control number 1212–0059.

The PBGC is revising the collections of information to provide for a new alternative means of electronic filing of premium information, in addition to the existing MyPAA application. The PBGC intends to establish standards, for the structure and submission of files containing premium filing information, that can be incorporated in private-sector premium filing software to permit users of such software to submit their

premium filings to the PBGC electronically. This alternative e-filing method is being developed in connection with an anticipated PBGC proposal to require electronic premium filing in the near future.

In connection with and as part of the new filing standards, the PBGC is providing for a new method for certifying premium filings made using private-sector software. Currently, a plan's premium filing must be certified by the plan administrator and, in many cases, also by an enrolled actuary. My PAA, which uses interactive software on the PBGC's Web site, permits both a plan administrator and an enrolled actuary to certify the same filing, but the PBGC anticipates that private-sector software developers will find it difficult or impossible to implement such a feature, which requires both the plan administrator and the enrolled actuary to access the same filing electronically.

Accordingly, the PBGC is introducing a new premium filing certification methodology for premium filings made with private-sector software. The new methodology requires one responsible person (who may but need not be either the plan administrator or the enrolled actuary) to certify a private-sector software premium filing. If the responsible person is not the plan administrator, the certification will also state that the responsible person is authorized to act by the plan administrator and has a written representation from the plan administrator that the filing is proper. If the responsible person is not the enrolled actuary, the certification for a filing that includes actuarial items (variable-rate premium computations or certain variable-rate premium exemptions) will also state that the responsible person has a written representation from the enrolled actuary that the actuarial items in the filing are proper. The responsible person may be either the plan administrator or the enrolled actuary, and if not, must be at an appropriate level of authority, such as an officer of the plan sponsor.

The PBGC intends to request that OMB approve this revision of the collections of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The PBGC estimates that it will receive premium filings annually from about 28,900 plan administrators and that the total annual burden of the collection of information will be about 3,478 hours and $18,172,550. (These estimates include paper and electronic filings.)

The PBGC is soliciting public comments to—

- Evaluate whether the collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of collection of information 1212–0009, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collections of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Issued in Washington, DC, this 19th day of November, 2004.

Stuart A. Sirkin,

Director, Corporate Policy and Research Department, Pension Benefit Guaranty Corporation.

[FR Doc. 04–26051 Filed 11–23–04; 8:45 am]

BILLING CODE 7708–01–P

RAILROAD RETIREMENT BOARD

2005 Railroad Experience Rating Proclamations, Monthly Compensation Base and Other Determinations

AGENCY: Railroad Retirement Board.

ACTION: Notice.

SUMMARY: Pursuant to section 8(c)(2) and section 12(r)(3) of the Railroad Unemployment Insurance Act (Act) (45 U.S.C. 358(c)(2) and 45 U.S.C. 362(r)(3), respectively), the Board gives notice of the following:

1. The balance to the credit of the Railroad Unemployment Insurance (RUI) Account, as of June 30, 2004, is $98,626,277.48;

2. The September 30, 2004, balance of any new loans to the RUI Account, including accrued interest, is zero;

3. The system compensation base is $3,119,631,126.68 as of June 30, 2004;

4. The cumulative system unallocated charge balance is ($257,789,781.80) as of June 30, 2004;

5. The pooled credit ratio for calendar year 2005 is zero;

6. The pooled charged ratio for calendar year 2005 is zero;

7. The surcharge rate for calendar year 2005 is 1.5 percent;

8. The monthly compensation base under section 1(i) of the Act is $1,150 for months in calendar year 2005;

9. The amount described in section 1(k) of the Act as ''2.5 times the monthly compensation base'' is $2,875 for base year (calendar year) 2005;

10. The amount described in section 2(c) of the Act as ''an amount that bears the same ratio to $775 as the monthly compensation base for that year as computed under section 1(i) of this Act bears to $600'' is $1,485 for months in calendar year 2005;

11. The amount described in section 3 of the Act as ''2.5 times the monthly compensation base'' is $2,875 for base year (calendar year) 2005;

12. The amount described in section 4(a–2)(i)(A) of the Act as ''2.5 times the monthly compensation base'' is $2,875 with respect to disqualifications ending in calendar year 2005;

13. The maximum daily benefit rate under section 2(a)(3) of the Act is $56 with respect to days of unemployment and days of sickness in registration periods beginning after June 30, 2005.

DATES: The balance in notice (1) and the determinations made in notices (3) through (7) are based on data as of June 30, 2004. The balance in notice (2) is based on data as of September 30, 2004. The determinations made in notices (5) through (7) apply to the calculation, under section 8(a)(1)(C) of the Act, of employer contribution rates for 2005. The determinations made in notices (8) through (12) are effective January 1, 2005. The determination made in notice (13) is effective for registration periods beginning after June 30, 2005.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611–2092.

FOR FURTHER INFORMATION CONTACT: Marla L. Huddleston, Bureau of the Actuary, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611–2092, telephone (312) 751–4779.

SUPPLEMENTARY INFORMATION: The RRB is required by section 8(c)(1) of the Railroad Unemployment Insurance Act (Act) (45 U.S.C. 358(c)(1)) as amended by Public Law 100–647, to proclaim by October 15 of each year certain system-wide factors used in calculating experience-based employer contribution rates for the following year. The RRB is further required by section 8(c)(2) of the Act (45 U.S.C. 358(c)(2)) to publish the amounts so determined and proclaimed. The RRB is required by section 12(r)(3) of the Act (45 U.S.C. 362(r)(3)) to publish by December 11, 2004, the computation of the calendar year 2005 monthly compensation base (section 1(i) of the Act) and amounts described in

sections 1(k), 2(c), 3 and 4(a–2)(i)(A) of the Act which are related to changes in the monthly compensation base. Also, the RRB is required to publish, by June 11, 2005, the maximum daily benefit rate under section 2(a)(3) of the Act for days of unemployment and days of sickness in registration periods beginning after June 30, 2005.

Surcharge Rate

A surcharge is added in the calculation of each employer's contribution rate, subject to the applicable maximum rate, for a calendar year whenever the balance to the credit of the RUI Account on the preceding June 30 is less than the greater of $100 million or the amount that bears the same ratio to $100 million as the system compensation base for that June 30 bears to the system compensation base as of June 30, 1991. If the RUI Account balance is less than $100 million (as indexed), but at least $50 million (as indexed), the surcharge will be 1.5 percent. If the RUI Account balance is less than $50 million (as indexed), but greater than zero, the surcharge will be 2.5 percent. The maximum surcharge of 3.5 percent applies if the RUI Account balance is less than zero.

The system compensation base as of June 30, 1991 was $2,763,287,237.04. The system compensation base for June 30, 2004 was $3,119,631,126.68. The ratio of $3,119,631,126.68 to $2,763,287,237.04 is 1.12895651. Multiplying 1.12895651 by $100 million yields $112,895,651. Multiplying $50 million by 1.12895651 produces $56,447,826. The Account balance on June 30, 2004, was $98,626,277.48. Accordingly, the surcharge rate for calendar year 2005 is 1.5 percent.

Monthly Compensation Base

For years after 1988, section 1(i) of the Act contains a formula for determining the monthly compensation base. Under the prescribed formula, the monthly compensation base increases by approximately two-thirds of the cumulative growth in average national wages since 1984. The monthly compensation base for months in calendar year 2005 shall be equal to the greater of (a) $600 or (b) $600 [1 + {(A—37,800)/56,700}], where A equals the amount of the applicable base with respect to tier 1 taxes for 2005 under section 3231(e)(2) of the Internal Revenue Code of 1986. Section 1(i) further provides that if the amount so determined is not a multiple of $5, it shall be rounded to the nearest multiple of $5.

The calendar year 2005 tier 1 tax base is $90,000. Subtracting $37,800 from $90,000 produces $52,200. Dividing $52,200 by $56,700 yields a ratio of 0.92063492. Adding one gives 1.92063492. Multiplying $600 by the amount 1.92063492 produces the amount of $1,152.38, which must then be rounded to $1,150. Accordingly, the monthly compensation base is determined to be $1,150 for months in calendar year 2005.

Amounts Related to Changes in Monthly Compensation Base

For years after 1988, sections 1(k), 2(c), 3 and 4(a–2)(i)(A) of the Act contain formulas for determining amounts related to the monthly compensation base.

Under section 1(k), remuneration earned from employment covered under the Act cannot be considered subsidiary remuneration if the employee's base year compensation is less than 2.5 times the monthly compensation base for months in such base year. Multiplying 2.5 by the calendar year 2005 monthly compensation base of $1,150 produces $2,875. Accordingly, the amount determined under section 1(k) is $2,875 for calendar year 2005.

Under section 2(c), the maximum amount of normal benefits paid for days of unemployment within a benefit year and the maximum amount of normal benefits paid for days of sickness within a benefit year shall not exceed an employee's compensation in the base year. In determining an employee's base year compensation, any money remuneration in a month not in excess of an amount that bears the same ratio to $775 as the monthly compensation base for that year bears to $600 shall be taken into account.

The calendar year 2005 monthly compensation base is $1,150. The ratio of $1,150 to $600 is 1.91666667. Multiplying 1.91666667 by $775 produces $1,485. Accordingly, the amount determined under section 2(c) is $1,485 for months in calendar year 2005.

Under section 3, an employee shall be a ''qualified employee'' if his/her base year compensation is not less than 2.5 times the monthly compensation base for months in such base year. Multiplying 2.5 by the calendar year 2005 monthly compensation base of $1,150 produces $2,875. Accordingly, the amount determined under section 3 is $2,875 for calendar year 2005.

Under section 4(a–2)(i)(A), an employee who leaves work voluntarily without good cause is disqualified from receiving unemployment benefits until he has been paid compensation of not less than 2.5 times the monthly compensation base for months in the calendar year in which the disqualification ends. Multiplying 2.5 by the calendar year 2005 monthly compensation base of $1,150 produces $2,875. Accordingly, the amount determined under section 4(a–2)(i)(A) is $2,875 for calendar year 2005.

Maximum Daily Benefit Rate

Section 2(a)(3) contains a formula for determining the maximum daily benefit rate for registration periods beginning after June 30, 1989, and after each June 30 thereafter.

Legislation enacted on October 9, 1996, revised the formula for indexing maximum daily benefit rates. Under the prescribed formula, the maximum daily benefit rate increases by approximately two-thirds of the cumulative growth in average national wages since 1984.

The maximum daily benefit rate for registration periods beginning after June 30, 2005, shall be equal to 5 percent of the monthly compensation base for the base year immediately preceding the beginning of the benefit year. Section 2(a)(3) further provides that if the amount so computed is not a multiple of $1, it shall be rounded down to the nearest multiple of $1.

The calendar year 2004 monthly compensation base is $1,130. Multiplying $1,130 by 0.05 yields $56.50, which must then be rounded down to $56. Accordingly, the maximum daily benefit rate for days of unemployment and days of sickness beginning in registration periods after June 30, 2005, is determined to be $56.

Dated: November 17, 2004.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 04–25973 Filed 11–23–04; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application of Southwest Gas Corporation To Withdraw Its Common Stock, $1.00 Par Value, From Listing and Registration on the Pacific Exchange, Inc. File No. 1–07850

November 18, 2004.

On November 3, 2004, Southwest Gas Corporation, a Nevada corporation (''Issuer''), filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 12d2–2(d)

[1] 15 U.S.C. 78*l*(d).

thereunder,[2] to withdraw its common stock, $1.00 par value (''Security''), from listing and registration on the Pacific Exchange, Inc. (''PCX'').

The Board of Directors of the Issuer approved a resolution on May 5, 2004 to withdraw the Issuer's Security from listing on the PCX. The Issuer states that the reasons for its decision to withdraw its Security from the PCX are as follows: (i) The Issuer needs to reduce costs, as well as administrative time and expense, associated with having its Security listed on multiple exchanges; (ii) the common stock is also listed on the New York Stock Exchange, Inc. (''NYSE'') which maintains the principal listing of the Issuer's common stock; (iii) since the Issuer is listed on more than one exchange, the Issuer has been paying listing and other fees and expenses associated with maintaining its listing on both exchanges; (iv) the Issuer's management has been required to focus on the listing and maintenance rules, as well as ongoing amendments to the rules and regulations of both exchanges; this, combined with the changing regulatory landscape that all public companies face as the result of the Sarbanes-Oxley Act of 2002, incrementally increased the amount of administrative time and expense that management has spent in connection with maintaining the listing of the Issuer's Security; and (v) by withdrawing the Security from the PCX, the Issuer will be able to lessen the administrative burden currently faced by the Issuer's management and reduce the related expenses.

The Issuer stated in its application that it has complied with applicable rules of the PCX Rule 5.4(b), by complying with all applicable laws in effect in the State of Nevada and by providing the PCX with the required documents governing the removal of securities from listing and registration on the PCX. The Issuer's application relates solely to the withdrawal of the Security from listing on the PCX and shall not affect its continued listing on the NYSE or its obligation to be registered under Section 12(b) of the Act.[3]

Any interested person may, on or before December 14, 2004 comment on the facts bearing upon whether the application has been made in accordance with the rules of the PCX, and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters may be submitted by either of the following methods:

Electronic Comments

- Send an e-mail to *rule-comments@sec.gov*. Please include the File Number 1–07850 or;

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. All submissions should refer to File Number 1–07850. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/delist.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. E4–3331 Filed 11–23–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27911]

Filing Under the Public Utility Holding Company Act of 1935, as amended (''Act'')

November 18, 2004.

Notice is hereby given that the following filing(s) has/have been made with the Commission under provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by December 13, 2004, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After December 13, 2004, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Allegheny Energy, Inc., et al. (70–7888)

Allegheny Energy, Inc. (''Allegheny''), a registered holding company; Allegheny Energy Supply Company, LLC (''AE Supply''), a registered holding company and public utility company subsidiary of Allegheny;[1] Allegheny's wholly-owned public-utility company subsidiaries, Monongahela Power Company (''Monongahela Power''), Mountaineer Gas Company (''Mountaineer''), The Potomac Edison Company (''Potomac Edison''), West Penn Power Company (''West Penn''), and Allegheny Generating Company (''AGC''); and the Allegheny system service company, Allegheny Energy Service Corporation (''AESC,'' and collectively, ''Applicants''), 800 Cabin Hill Drive Greensburg, PA 15601, have filed an application-declaration (''Application'') under sections 6, 7, 9(a), 12(b), and 13 of the Act and rules 43, 45, 54, 86, 87, 90, 91, and 100 under the Act.

The Applicants request authority to continue the current Allegheny system money pool (''Money Pool'') through April 30, 2005. The Commission has previously authorized the operation of the Money Pool through December 31, 2004.

The Allegheny system has three regulated electric utility companies, West Penn, Monongahela Power, and Potomac Edison Company (collectively, ''Operating Companies''), and a regulated gas utility company, Mountaineer, which is a wholly-owned subsidiary of Monongahela Power (all collectively d/b/a ''Allegheny Power'').[2]

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 17 CFR 200.30–3(a)(1).

[1] AE Supply is a public utility company within the meaning of the Act, but it is not subject to state regulation.

[2] On August 4, 2004, Allegheny announced it had entered into an agreement to sell Mountaineer and

P='68425'≤Allegheny Power delivers electric energy to approximately 1.6 million customers in parts of Maryland, Ohio, Pennsylvania, Virginia, and West Virginia and natural gas to approximately 230,000 customers in West Virginia. AGC is jointly owned by Monongahela Power and AE Supply. Its sole asset is a 40 percent undivided interest in a pumped-storage hydroelectric station located in Bath County, Virginia. All of AGC's revenues are derived from sales from its share of this facility's generating capacity to AE Supply and Monongahela Power. AE Supply is the principal electric generating company for the Allegheny system. AE Supply provides power to West Penn, Potomac Edison, and Monongahela Power to serve their customers in Pennsylvania, Maryland, Virginia, and Ohio and to serve the retail load of Potomac Edison in West Virginia. AESC is the Allegheny system service company. Among other things, it administers the Money Pool.

In a series of orders [3] (collectively, ''Prior Money Pool Orders''), the Applicants were authorized, among other things, to establish and participate in the Money Pool through December 31, 2004. The Applicants request authority to continue the Money Pool through April 30, 2005, subject to substantially the same terms and conditions set forth in the Prior Money Pool Orders.[4] The applicants request that the Commission authorize (i) Monongahela Power, Mountaineer, Potomac Edison, and West Penn to continue participation in the Money Pool as both lenders and borrowers to the extent not exempt under rule 52; (ii) AGC to continue participation in the Money Pool as a borrower only, to the extent not exempt under rule 52; and (iii) Allegheny and AE Supply to continue participation in the Money Pool as lenders only.

The Money Pool will continue to be administered on behalf of the Money Pool Applicants by AESC and under the direction of an officer of AESC. AESC will not be a participant in the Money Pool. The Money Pool will consist principally of surplus funds received from the Money Pool Applicants.

The Applicants do not propose any material changes to the operation of the Money Pool as currently authorized. Participants will be parties to the Allegheny Energy System Money Pool Agreement. Transactions under the Money Pool will be designed to match, on a daily basis, the surplus funds of the pool participants with the short-term borrowing requirements of the pool participants (other than the pool participants who are lenders only). The Applicants believe that the cost of the proposed borrowings through the Money Pool generally will be more favorable to the borrowing participants than the comparable cost of external short-term borrowings, and the yield to the participants contributing available funds to the Money Pool generally will be higher than the typical yield on short-term investments.

The funds available through the Money Pool will be loaned on a short-term basis to those eligible pool participants that have short-term debt requirements. If no short-term requirements match the amount of funds that are available for the Money Pool for the period the funds are available, AESC will invest the funds, directly or indirectly, as described below and will allocate the interest earned on these investments among the pool participants providing these funds on a pro rata basis according to the amount of funds each provided:

(1) Direct of indirect obligations of the United States Government;

(2) Certificates of Deposit of commercial banks with assets exceeding $2.5 billion;

(3) Bankers acceptances of commercial banks with assets exceeding $2.5 billion;

(4) Commercial paper of companies having a minimum net worth of $150 million having a ''1'' commercial paper rating by at least two of the three recognized rating services (Moody's, Standard & Poor's, and Fitch);

(5) Taxable or tax exempt institutional money market funds with assets of at least $500 million which restrict investments to high quality money market instruments; and

(6) Such other investments as are permitted by section 9(c) of the Act and rule 40 under the Act.

All borrowings from and contributions to the Money Pool will be documented and will be evidenced on the books of each pool participant that is borrowing from or contributing surplus funds to the Money Pool. Any pool participant contributing funds to the Money Pool may withdraw those funds at any time without notice to satisfy its daily need for funds. All short-term debt through the Money Pool will be payable on demand, may be prepaid by any borrowing pool participant at any time without penalty, and will bear interest for both the borrower and lender. Interest income and expense will be calculated using the previous day's Fed Funds Effective Interest Rate (''Fed Funds Rate'') as quoted by the Federal Reserve Bank of New York, as long as this rate is at least, four basis points lower than the previous day's seven-day commercial paper rate as quoted by the same source. Whenever the Fed Funds Rate is not at least four basis points lower than the seven-day commercial paper rate, then the seven-day commercial paper rate minus four basis points should be used. Interest income and expense will be calculated daily and settled on a cash basis on the first business day of the following month.

Each of the Utility Applicants may use the proceeds it borrows from the Money Pool (i) for the interim financing of its construction and capital expenditure programs; (ii) for its working capital needs; (iii) for the repayment, redemption, or refinancing of its debt and preferred stock; (iv) to meet unexpected contingencies, payment and timing differences, and cash requirements; and (v) to otherwise finance its own business and for other lawful general corporate purposes. Each of the following companies requests authority to borrow up to an amount at any one time outstanding from the Money Pool as set forth below: AGC, $100 million; Monongahela Power, $125 million; Mountaineer, $100 million; Potomac Edison, $150 million; West Penn, $200 million.

PNM Resources, Inc. (70–10248)

PNM Resources, Inc. (''PNM Resources''), Alvarado Square, Albuquerque, NM 87158, an electric and gas public utility holding company has filed an application-declaration (''Application'') under sections 6(a), 7, 9(a), 10, 12(b), and 13 of the Act and rules 42–46, 90–91 and 54 under the Act.[5]

I. Introduction

A. PNM Resources and Its Subsidiaries

PNM Resources is a holding company that currently claims exemption from registration under section 3(a)(1) of the Act by rule 2 under the Act. PNM

all of Allegheny's West Virginia gas assets to a partnership composed of IGS Utilities LLC, IGS Holdings LLC, and affiliates of ArcLight Capital Partners, LLC.

[3] Holding Co. Act Release Nos. 25462 (Jan. 29, 1992), 25481 (Feb. 28, 1992), 25581 (July 14, 1992), 25919 (Nov. 5, 1993), 26418 (Nov. 28, 1995), 26506 (April 18, 1996), 26804 (Dec. 23, 1997), 27030 (May 19, 1999), 27084 (Oct. 8, 1999), 27475 (Dec. 17, 2001), 27585 (Oct. 24, 2002), and 27199 July 14, 2000).

[4] The Commission has authorized Mountaineer to participate in the Money Pool through December 31, 2005.

[5] PNM Resources states that on or before the official date of the order in this matter (''Order Date'') it will file a notice of registration complying with rule 1(a) under the Act.

Resources became a public utility holding company on December 31, 2001. PNM Resources' only public utility company subsidiary is Public Service Company of New Mexico (''PNM''), a New Mexico corporation. PNM is an electric and gas public utility company. It is engaged in the generation, transmission, and distribution of electric energy at retail in the State of New Mexico and makes sales for resale (''wholesale'' sales) of electricity in interstate commerce. PNM is also engaged in the distribution of natural gas in the State of New Mexico, which includes some off-system wholesale sales of natural gas. PNM had electric revenues for 2003 of $543,850,000, $51,952,000 and $550,382,000 for its retail, transmission, and wholesale electricity segments, respectively. Its natural gas operating revenues for 2003 were $358,267,000.

PNM Resources' current nonutility activities are conducted through Avistar, Inc. (''Avistar''), a company engaged in the developing and marketing of technologies for energy production and supply. PNM also factors its receivables through a financing subsidiary, PNM Receivables Corporation, but does not offer the service to non-affiliates. PNM Resources accordingly requests authority pursuant to sections 9 and 10 of the Act to continue to retain its interest in and fund the operation of PNM Receivables Corporation using the proceeds of the authorized financings.

Furthermore, PNM Resources has the following direct inactive nonutility subsidiaries: EIP Refunding Corporation, Paragon Resources, Inc., PNM Electric & Gas Services, Inc., Sunbelt Mining Co. Inc., Sunterra Gas Gathering Company and Sunterra Gas Processing Company. PNM Resources also has the following indirect inactive nonutility subsidiaries: AMDAX.com (25% interest directly owned by Avistar), Gas Company of New Mexico (directly owned by Sunbelt Mining Co. Inc.), Meadows Resources, Inc. (directly owned by PNM) and its subsidiaries, Bellamah Associates, Ltd., Bellamah Community Development, Bellamah Holding Company, Bellamah Investors Ltd., and Republic Holding Company. PNM Resources states that these subsidiaries conduct no on-going business activities other than winding up existing obligations and that Commission authorization will be secured prior to any of these companies reinstating active business operations.

PNM is subject to the jurisdiction of the New Mexico Public Regulation Commission (''NMPRC''), with respect to its retail electric and gas rates, service, accounting, issuance of securities, construction of major new generation and transmission facilities and other matters regarding retail utility services provided in New Mexico.

PNM's principal business segments are wholesale operations (''Wholesale'') and utility operations. Utility operations include electric services, transmission services (''Transmission'') and gas services (''Gas''). In addition, PNM owns ''Merchant Plant'' (authorized generation facilities that are not included in rate base) that is subject to a Global Electric Settlement Agreement that was entered into on October 10, 2002 (''Global Electric Settlement'') and approved by the NMPRC.

Wholesale consists of the generation and sale of excess electricity into the wholesale market based on three product lines that include long-term contracts, forward sales and short-term sales. The ''regulated generation'' (generation in rate base),''unregulated generation'' (certain generation excluded from rate base) and ''Merchant Plant'' (including certain generation excluded from rate base) are jointly dispatched in order to improve reliability, provide the most economic power to retail customers, and maximize profits on any wholesale transactions. From time to time, Wholesale also makes purchases of energy.

PNM provides retail electric service to a large area of north central New Mexico, including the cities of Albuquerque and Santa Fe, and certain other areas of New Mexico. Customers' rates for retail electric service are set by the NMPRC based on the provisions of the Global Electric Settlement through 2007. PNM's power generation facilities are jointly dispatched under common control in order to serve PNM's electric utility customers economically and reliably. PNM owns or leases generation located in the States of Arizona and New Mexico within the Western Electricity Coordinating Council (''WECC'')[6] region, a National Electric Reliability Council region including much of the Western United States and portions of Canada and Mexico. PNM is interconnected with the Southwest Power Pool (''SPP''). Generation included within the SPP is eligible for inclusion as Merchant Plant. PNM experienced a peak electrical demand on its system of 1661 MW in 2003. PNM owns or leases 1742 MW of generating capacity. Additional capacity is purchased from third parties under certain power purchase agreements that may be accounted for as leases, for a total of 2074 MW available capacity.

Transmission consists of the transmission of electricity over transmission lines owned or leased by PNM, interconnected with other utilities in New Mexico and south and east into Texas, west into Arizona and north into Colorado and Utah. PNM owns or leases approximately 3000 circuit miles of transmission lines. PNM owns and operates in excess of 8000 miles of distribution lines excluding street lighting in New Mexico.

The Gas segment includes the transportation and distribution of natural gas to end users, including end users in most of the major communities in New Mexico, including Albuquerque and Santa Fe. Gas's customer base includes both sales-service customers and transportation-service customers. PNM Resources states that Gas derives its supplies from common sources of supply within New Mexico and the region and operates as an integrated system. From time to time, the Gas segment makes off-system sales of natural gas incidental to its natural gas operations.

The Merchant Plant owned by PNM constitutes utility assets within the meaning of the Act,[7] and will be available through joint dispatch to support service to the retail customers of PNM. PNM's Merchant Plant activities are governed by the Global Electric Settlement.

II. Current Request

PNM Resources seeks the following authority beginning with the Order Date through December 31, 2007 (''Authorization Period'') for:

(A) PNM Resources to increase its capitalization in the aggregate amount of $1.5 billion (''Financing Limit'') over and above its capitalization as of December 31, 2003, other than for exchanging, refunding or replacing securities, where capitalization is not increased, through the issuance and/or sale of common stock, preferred stock, preferred securities, equity-linked securities, long-term debt and short-term debt, or securities which are convertible into any such securities, whether directly or through one or more financing conduits;[8]

[6] The WECC was formed on April 18, 2002, by the merger of the Western Systems Coordinating Council, the Southwest Regional Transmission Council and the Western Regional Transmission Association. It coordinates and supports electric system reliability and open power transmission access throughout its service area, encompassing 1.8 million square miles.

[7] PNM Resources to date has no aggregate investment in any Exempt Wholesale Generators (''EWGs''), as defined in section 32 of the Act.

[8] For the purpose of calculating the amount of the $1.5 billion authorization used at any one time,

(B) PNM Resources to provide performance and financial guarantees, and other credit support for all of its subsidiaries, as described below, in an aggregate amount not to exceed $300 million at any time outstanding;

(C) PNM Resources to issue and sell common stock pursuant to direct stock purchase and dividend reinvestment plans, incentive compensation plans and other employee benefit plans (included under the issuances and sales of common stock authorized in Paragraph (A) above);

(D) PNM Resources to engage in certain cash management activities as described below;

(E) PNM Resources to use financing conduits or subsidiaries to issue or sell debt or equity securities or securities which are convertible into any such securities on PNM Resources' behalf either by PNM Resources owning such conduits or subsidiaries or guaranteeing the obligations of such conduits or subsidiaries as described below;

(F) PNM Resources to enter into transactions to manage interest rate and equity price risk with regard to the issuance of securities as described below;

(G) PNM Resources to invest up to $300 million in certain natural gas gathering, storage, transmission, other fuel resources, processing storage and transportation assets (''Energy Assets'');

(H) PNM Resources to change the capital stock of subsidiaries as described below;

(I) PNM Resources to exchange, refund or replace existing securities where capitalization is not increased as a result over that in place at December 31, 2003; and

(J) PNM Resources to provide services to its subsidiaries pursuant to section 13(a) of the Act as described below.

III. Parameters for Financing Authorization

The following general terms will be applicable where appropriate to the financing transactions requested:

(A) Common Equity Ratio. PNM Resources states that at all times during the Authorization Period each of PNM Resources and PNM will maintain common equity (as reflected in the most recent Form 10–K or Form 10–Q filed with the Commission) of at least 30% of its consolidated capitalization (common equity, preferred stock and long-term and short-term debt); provided that PNM Resources will in any event be authorized to issue common stock to the extent otherwise authorized in this Application.[9]

(B) Investment Grade Ratings. PNM Resources will not issue any securities, other than common stock, commercial paper, member interest, short-term bank debt (with a maturity of one year or less) or securities issued for the purpose of funding intra-system financings, pursuant to the authority conferred pursuant to this Application, unless upon original issuance (1) the security to be issued, if rated, is rated at least investment grade; and (2) all outstanding securities of PNM Resources that are rated are rated investment grade (the ''Investment Grade Condition''). For purposes of this provision, a security will be deemed to be rated investment grade if it is rated investment grade by at least one nationally recognized statistical rating organization, as defined in rule 15c3–1(c)(2)(vi)(F) under the Securities Exchange Act of 1934. PNM Resources further requests that the Commission reserve jurisdiction over the issuance of any securities that do not satisfy the Investment Grade Condition.

(C) Effective Cost of Money on Financings. The effective cost of capital for long-term debt, short-term debt, preferred stock, preferred securities and equity-linked securities will not exceed competitive market rates available at the time of issuance for securities having the same or reasonably similar terms and conditions issued by similar companies of reasonably comparable credit quality; provided that in no event will the effective cost of capital on (i) any such long-term debt securities exceed 500 basis points over comparable term U.S. Treasury securities (''Treasury Security''); or (ii) any such short-term debt securities exceed 300 basis points over London Interbank Offered Rate. The dividend and distribution rate on any series of preferred stock, preferred securities or equity-linked securities will not exceed at the time of issuance 700 basis points over a Treasury Security.

(D) Maturity. The final maturity of any long-term debt securities will not exceed 50 years. Preferred securities will be redeemed no later than 50 years after issuance, unless such preferred security is perpetual in duration. Short-term debt will have a maturity of no more than 1 year.

(E) Issuance Expenses. The underwriting fees, commissions or other similar remuneration paid in connection with the non-competitive issue, sale or distribution of securities pursuant to this Application will not exceed the greater of (1) 500 basis points of the principal or face amount of the securities being issued or gross proceeds of the financing or (2) the competitive market rates which are consistent with similar securities of comparable credit quality and maturities issued by other companies.

(F) Use of Proceeds. The proceeds from the sale of securities issued by PNM Resources pursuant to this Application will be used for general corporate purposes including (1) the financing of the capital expenditures of the PNM Resources system, (2) the financing of working capital requirements of the PNM Resources system, (3) direct or indirect investment in companies or assets the acquisition of which are either exempt under the Act or by Commission rule or have been authorized by the Commission, (4) cash management activities and (v) other lawful purposes.

IV. Description of Requested Financing

As more fully described below, PNM Resources requests authorization to obtain funds externally through sales of equity, equity linked, preferred and/or debt securities in accordance with the authority granted by the Commission.[10] PNM Resources also requests authority to issue common stock to third parties in consideration for the acquisition by PNM Resources of equity or debt securities of a company being acquired pursuant to an exemption under the Act, or pursuant to a Commission rule or specific authorization by another Commission order. In addition, PNM Resources seeks, to the extent authorization is required, the flexibility to enter into certain hedging transactions to manage interest rate and equity price risk.

A. Equity Securities

1. Common Stock (Including Stock Purchase Contracts/Units)

From time to time during the Authorization Period, subject to the limits and conditions specified in this Application, PNM Resources seeks authority to issue and sell up to 60 million additional shares of its common stock or securities convertible into

PNM Resources will calculate capitalization on a non-consolidated basis and will exclude retained earnings and accumulated other comprehensive income, as well as the amount of securities issued for purposes of refunding or replacing other outstanding securities where PNM Resources' capitalization is not increased as a result.

[9] As of June 30, 2004, consolidated common equity as a percentage of total capitalization for PNM Resources and PNM was 52.3% and 50.7%, respectively.

[10] Although not limited to the securities described in PNM Resources' Universal Shelf S–3 incorporated by reference in this Application, the authorization sought includes all of the securities described in the shelf registration.

common stock (1) through solicitations of proposals from underwriters or dealers, (2) through negotiated transactions with underwriters or dealers, (3) directly to a limited number of purchasers or to a single purchaser, and/or (4) through agents. The price applicable to additional shares sold in any such transaction will be based on several factors, including the current market price of the common stock and prevailing capital market conditions.

PNM Resources also seeks authority to issue and sell from time to time stock purchase contracts (''Stock Purchase Contracts''), including contracts obligating holders to purchase from PNM Resources and/or PNM Resources to sell to the holders, a specified number of shares at an aggregate offering price of PNM Resources' common stock at a future date. The consideration per share of common stock may be fixed at the time the Stock Purchase Contracts are issued or may be determined by reference to a specific formula set forth in the Stock Purchase Contracts. The Stock Purchase Contracts may be issued separately or as part of units (''Stock Purchase Units'') consisting of a stock purchase contract and debt and/or preferred securities of PNM Resources and/or debt obligations of non-affiliates, including U.S. Treasury securities, securing holders' obligations to purchase the common stock of PNM Resources under the Stock Purchase Contracts. The Stock Purchase Contracts may require holders to secure their obligations under the contracts in a specified manner.

PNM Resources may also issue common stock, securities convertible into common stock, warrants and other stock purchase rights exercisable for common stock as consideration, in whole or in part, for acquisitions by PNM Resources of securities of businesses or the assets of such businesses, the acquisition of which (1) is exempt under the Act or by Commission rule or (2) has been authorized by prior Commission order issued to PNM Resources, subject in either case to applicable limitations on total investments in any such businesses.

PNM Resources requests authority, from time to time during the Authorization Period, to issue and/or acquire in open market transactions or by some other method, which complies with applicable law and Commission interpretations then in effect, shares of PNM Resources common stock for its Omnibus Performance Equity Plan and other stock plans, pension trusts or other PNM Resources direct stock purchase and dividend reinvestment plans or similar plans adopted in the future without additional prior Commission order. PNM Resources further requests authority to issue and sell common stock to PNM customers consistent with existing charter authority and the requirements of applicable state and federal securities laws pursuant to a plan to be adopted during the Authorization Period without additional prior Commission order. Stock transactions of the variety described above would be treated the same as other stock transactions permitted under this Application.

2. Preferred Securities

Subject to the limits and conditions specified in this Application, PNM Resources also seeks authority to issue and sell preferred securities in one or more series. Preferred securities or securities convertible into preferred securities of any series (1) will have a specified par or stated value or liquidation value per security, (2) will carry a right to periodic cash dividends and/or other distributions, subject among other things, to funds being legally available, (3) may be subject to optional and/or mandatory redemption, in whole or in part, at par or at various premiums above the par or stated liquidation value of the securities, (4) may be convertible or exchangeable into common stock of PNM Resources, preferred securities or unsecured debt that PNM Resources is otherwise authorized to issue by Commission order directly, or indirectly through financing conduits on behalf of PNM Resources, (5) and may bear such further rights, including voting, preemptive or other rights, and other terms and conditions, as set forth in the applicable certificate of designation, purchase agreement and/or similar instruments governing the issuance and sale of such series of preferred securities.

B. Debt Securities

1. Short-Term Notes

Subject to the limits and conditions in this Application, PNM Resources seeks authority to make unsecured short-term borrowings from banks or other financial institutions. Such borrowings will be evidenced by (1) ''transactional'' promissory notes to be dated the date of such borrowings and to mature not more than one year after or (2) ''grid'' promissory notes evidencing all outstanding borrowings from the respective lender, to be dated as of the date of the first borrowing evidenced by the note, with each such borrowing maturing not more than one year after. Any such note may or may not be prepayable, in whole or in part, with or without a premium in the event of prepayment. PNM Resources notes that, at any given time, some or all of its outstanding short-term notes will be issuable in connection with the establishment of back-up credit facilities to support PNM Resources' commercial paper program but that such credit facilities will not be drawn upon and no borrowings will occur under those programs except in certain limited circumstances at which time obligations under the related commercial paper will be paid. PNM Resources states that short-term notes issued in connection with the establishment of commercial paper back-up facilities backstop and duplicate commercial paper issuances and should not be counted against its Financing Limit unless and until an actual borrowing occurs under the related credit facility. Additionally, Applicants request that with respect to any ''grid'' notes issued by PNM Resources, only the amount actually outstanding under the notes at any given time shall be considered a borrowing.

2. Commercial Paper

Subject to the limits and conditions in this Application, PNM Resources also seeks authority to issue and sell commercial paper through one or more dealers or agents or directly to a limited number of purchasers. PNM Resources proposes to issue and sell the commercial paper at market rates with varying maturities not to exceed 365 days. The commercial paper will be in the form of book-entry unsecured promissory notes (and/or pursuant to an underlying master note with a trust company which may not state a maturity) with varying denominations of not less than $1,000 each. In commercial paper sales effected on a discount basis, no commission or fee will be payable; however, the purchasing dealer will re-offer the commercial paper at a rate less than the rate offered to PNM Resources. The discount rate to dealers will not exceed the maximum discount rate per annum prevailing at the date of issuance for commercial paper of comparable quality and the same maturity. The purchasing dealer will re-offer the commercial paper in such a manner as not to constitute a public offering within the meaning of the Securities Act of 1933, as amended (the ''Securities Act'') or otherwise so as to be exempt from registration under the Securities Act.

3. Long-Term Notes

Subject to the limits and conditions in this Application, PNM Resources also seeks authority to issue and sell long-term unsecured debt securities (''Notes'') in one or more series. Notes of any series may be either senior or subordinated obligations of PNM Resources. Notes of any series (1) will have maturities of at least 12 months, (2) may be subject to optional and/or mandatory redemption, in whole or in part, at par or at various premiums above the principal amount, (3) may be entitled to mandatory or optional sinking fund provisions, and (4) may be convertible or exchangeable into common stock of PNM Resources. Interest accruing on Notes of any series may be fixed or floating or ''multi-modal'' (where the interest is periodically reset, alternating between fixed and floating interest rates for each reset period, with all accrued and unpaid interest together with interest becoming due and payable at the end of each such reset period, or at maturity). Notes may be issued under one or more indentures to be entered into between PNM Resources and financial institutions acting as trustee(s); supplemental indentures may be executed in respect of separate offerings of one or more series of Notes.

Notes may be issued in private or public transactions. With respect to the former, Notes of any series may be issued and sold directly to one or more purchasers in privately negotiated transactions or to one or more investment banking or underwriting firms or other entities who would resell the Notes without registration under the Securities Act in reliance upon one or more applicable exemptions from registration. From time to time, PNM Resources may also issue and sell Notes of one or more series to the public either (1) through underwriters selected by negotiation or competitive bidding or (2) through selling agents acting either as agent or as principal for resale to the public either directly or through dealers. Furthermore, Notes may be issued to public agencies or authorities, political subdivisions or instrumentalities that provide industrial revenue bond or pollution control revenue bond or similar financing to PNM Resources or its financing conduits or intermediate subsidiaries (as defined below).

The maturity dates, interest rates, redemption and sinking fund provisions, if any, with respect to the Notes of a particular series, as well as any associated placement, underwriting, structuring or selling agent fees, commissions and discounts, if any, will be established by negotiation or competitive bidding and reflected in the applicable purchase agreement or underwriting agreement setting forth such terms.[11]

C. Financing Conduits

In addition to issuing any of the debt or equity securities directly, PNM Resources requests approval (to the extent such approval may be required under the Act) to form one or more entities for the primary purpose of issuing and selling any of the foregoing securities, lending, transferring the proceeds to PNM Resources or an entity designated by PNM Resources, and engaging in incidental transactions, subject to the limits and conditions of this Application.

The proposed entities will comprise one or more financing entities (each, a ''Financing Entity'') and one or more special-purpose entities (each, a ''Special-Purpose Entity,'' and together with Financing Entities, ''Financing Conduits''). In either case the entities' businesses may include issuing and selling securities on behalf of PNM Resources or a PNM Resources' affiliate. Any securities issued by the Financing Conduits may be guaranteed by PNM Resources or such affiliate, either directly or indirectly. Such Financing Conduits may be constituted as corporations, partnerships, limited liability companies, trusts or other entities.

PNM Resources would acquire a portion of the outstanding shares of common stock or other equity interests of the Financing Conduit for an amount not less than the minimum required by applicable law. A primary function of the Financing Conduit will be effecting financing transactions with third parties for the benefit of PNM Resources or its affiliates. As an alternative in a particular instance to PNM Resources directly issuing debt or equity securities, or through a Special-Purpose Entity, PNM Resources may determine to use a Financing Entity as the nominal issuer of the particular debt or equity security. In that circumstance, PNM Resources or its affiliate may provide a full guarantee or other credit support with respect to the securities issued by the Financing Entity, the proceeds of which would be lent, dividended or otherwise transferred to PNM Resources or an entity designated by PNM Resources.

[11] As of June 30, 2004, PNM Resources has no outstanding long-or short-term debt securities.

D. Interest Rate and Equity Price Risk Management

To the extent authorization is required under the Act, PNM Resources requests authority to manage equity price and interest rate risk through the performance, entering into, purchasing and selling of various risk management instruments commonly used in today's capital markets, such as interest rate swaps, caps, collars, floors, options, forwards, treasury locks, forward starting interest rate swaps, futures, forward issuance agreements, call spread options, the sale and/or purchase of various call or put options or warrants and similar products designed to manage market, price, rate or credit risks (collectively ''Hedging Instruments'').

PNM Resources would enter into Hedging Instruments only with approved counterparties who at the date of execution of the agreement with PNM Resources are rated (or have a parent company providing a guarantee that is rated) at least investment grade, *i.e.*, ''BBB'' by Standard & Poors, Inc. or Fitch IBCA, Inc or ''Baa2'' by Moody's Investors Service (''Authorized Counterparties''). The derivative transactions will be for fixed periods and in no case will the notional principal amount exceed the principal amount of the underlying security. PNM Resources will not engage in ''leveraged'' or ''speculative'' derivative hedging transactions.

In addition, PNM Resources requests authorization to manage, maintain, remove and enter into hedging transactions with respect to anticipated securities offerings (the ''Anticipatory Hedges''), subject to certain limitations and restrictions. Such Anticipatory Hedges would only be entered into with Authorized Counterparties, and would be utilized to fix and/or limit the interest rate or equity price risk associated with any new issuance through (1) a forward sale of exchange-traded Hedge Instruments (a ''Forward Sale''), (2) the purchase of put options on Hedge Instruments (a ''Put Options Purchase''), (3) a Put Options Purchase in combination with the sale of call options Hedge Instruments (a ''Zero Cost Collar''), (4) transactions involving the purchase or sale, including short sales, of Hedge Instruments, or (5) some combination of a Forward Sale, Put Options Purchase, Zero Cost Collar and/or other derivative or cash transactions, including, but not limited to, structured notes, caps and collars, appropriate for the Anticipatory Hedges. Anticipatory Hedges may be executed on-exchange (''On-Exchange Trades'') with brokers

through the opening of futures and/or options positions traded on the Chicago Board of Trade or New York Mercantile Exchange, the opening of over-the-counter positions with one or more counterparties (''Off-Exchange Trades''), or a combination of On-Exchange Trades and Off-Exchange Trades. PNM Resources will determine the optimal structure of each Anticipatory Hedge transaction at the time of execution. In this regard, PNM Resources may decide to lock in interest rates and/or limit its exposure to interest rate increases.

Fees and commissions charged or required in connection with any interest rate or equity price risk management agreements will not exceed the then current market price. PNM Resources represents that each Hedging Instrument and Anticipatory Hedge will be treated for accounting purposes under generally accepted U.S. accounting principles. In particular, PNM Resources will comply with Statement of Financial Accounting Standards (''SFAS'') 133 (''Accounting for Derivative Instruments and Hedging Activities''), SFAS 138 (''Accounting for Certain Derivative Instruments and Hedging Activities'') or other accounting standards related to Hedging Instruments or Anticipatory Hedges as are adopted and implemented by the Financial Accounting Standards Board (''FASB''). PNM Resources states that Hedging Instruments and Anticipatory Hedges will qualify for hedge accounting under the current FASB standards in effect and as determined at the date on which Hedging Instruments or Anticipatory Hedges are entered.

E. Financial and Performance Guarantees

From time to time through the Authorization Period, PNM Resources requests authority to guarantee, obtain letters of credit, enter into financing arrangements and otherwise provide or maintain credit support (each, a ''Guarantee'') in respect of the debt or other securities or obligations, whether for payment and/or performance, of any or all of PNM Resources' subsidiary or associate companies (including any subsidiary or associate company formed or acquired at any time during the Authorization Period), and otherwise to further the business of PNM Resources, provided that the total amount of Guarantees at any time outstanding does not exceed $300 million (the ''PNM Resources Guarantee Limit''), and provided further, that (1) any Guarantees of EWGs and foreign utility companies (''FUCOs'') shall also be subject to PNM Resources' limitation on investment in EWGs and FUCOs; and (2) any Guarantees of energy-related companies within the meaning of rule 58 (''Rule 58 Companies'') shall also be subject to the aggregate investment limit of rule 58; and (3) any security guaranteed by PNM Resources shall itself be in compliance with the financing parameters authorized in this Application or otherwise exempt. The terms and conditions of any Guarantees, and the underlying liabilities, would be established at arm's-length based upon market conditions.

PNM Resources may charge a fee for each Guarantee provided on its behalf that is not greater than the cost, if any, of obtaining the liquidity necessary to perform the guarantee for the period of time the Guarantee remains outstanding.

In the event that PNM Resources issues any debt or equity securities authorized as part of this Application by means of any financing conduits or subsidiaries, PNM Resources may provide a full Guarantee in respect of the payment and other obligations of the financing conduit or subsidiary under the securities issued by it. Given that any securities nominally issued by any such financing conduit or subsidiary are in substance securities issued by PNM Resources itself, any securities issued by a financing conduit or subsidiary would count dollar-for-dollar against PNM Resources' financing authority. However, PNM Resources submits that any Guarantees of securities of financing conduits or subsidiaries will not count against the PNM Resources Guarantee Limit.

As stated above, PNM Resources requests the authority to extend its credit through entry into performance guarantees that will be a part of the definition of ''Guarantee'' provided in this Application. Such performance Guarantees may be in support of the obligations of affiliates undertaking the development or operation of projects authorized under the Act. However, performance Guarantees and certain other Guarantees may be in support of obligations that are not capable of exact quantification. In such cases, PNM Resources states that it will determine the exposure under such Guarantees for purposes of measuring compliance with the PNM Resources Guarantee Limit by appropriate means, including estimation of exposure based on loss experience or projected potential payment amounts.

V. Cash Management Activities

PNM Resources requests authorization to continue its existing cash management activities with surplus funds. Surplus funds would ordinarily be invested in one or more short-term investments including: (1) Obligations issued or guaranteed by the U.S. government and/or its agencies and instrumentalities; (2) commercial paper; (3) certificates of deposit; (4) bankers' acceptances; (5) repurchase agreements; (6) tax exempt notes; and (7) other investments that are permitted by section 9(c)(3) of the Act and rule 40 under the Act. PNM Resources maintains a program of investing up to $15 million in non-voting interests in certain funds designed to hedge capital market risks.

VI. Investments in Nonutility Subsidiaries and Energy Assets

PNM Resources requests authority to engage in certain activities described below relating to EWGs, FUCOs, exempt telecommunications companies, energy-related companies within the meaning of rule 58, and energy related companies approved by commission order and make additional investments in other nonutility subsidiaries approved by the Commission (collectively, ''Nonutility Subsidiaries''). To the extent activities described in this Application constitute the providing of goods, services or construction from one associate company to another in the PNM Resources system which would be subject to section 13(b) of the Act, these goods, services or construction will be provided at cost as defined in rules 90 and 91 unless an exemption from the at cost requirement is available under the Act or otherwise approved in the Commission's order in this matter.

PNM Resources requests authority to make additional investments in Nonutility Subsidiaries in the form of purchases of common stock and other securities, capital contributions, loans or open account advances, guarantees, or any combination of the foregoing. It is also contemplated that Nonutility Subsidiaries may issue securities from time to time under the exemption provided in rule 52 to investors other than PNM Resources for the purpose of financing their operations. Direct or indirect investments by PNM Resources in Nonutility Subsidiaries would be subject to the limitations applicable to investments for such subsidiaries.

In connection with existing and future nonutility businesses, PNM Resources will engage directly or through subsidiaries in preliminary development activities (''Development Activities'') and administrative and management activities (''Administrative Activities'') associated with such investments. Development Activities will be limited to: due diligence and design review; market studies; preliminary engineering; site inspection; preparation of bid proposals, including, posting of bid bonds; application for

required permits and/or regulatory approvals; acquisition of site options and options on other necessary rights; negotiation and execution of contractual commitments with owners of existing facilities, equipment vendors, construction firms, power purchasers, thermal ''hosts,'' fuel suppliers and other project contractors; negotiation of financing commitments with lenders and other third-party investors; and other preliminary activities as may be required in connection with the purchase, acquisition or construction of facilities or the securities of other companies. PNM Resources proposes to expend directly or through subsidiaries up to $300 million in the aggregate outstanding at any time during the Authorization Period on all Development Activities and Administrative Activities. Amounts expended in the development of projects leading to an investment in an Nonutility Subsidiaries will not count against the limitation on expenditures for Development Activities. Administrative Activities will include ongoing personnel, accounting, engineering, legal, financial and other support activities necessary to manage Development Activities and investments in subsidiaries.

PNM Resources requests authority to acquire directly or indirectly the securities of one or more corporations, trusts, partnerships, limited liability companies or other entities (collectively, ''Intermediate Subsidiaries''), which would be organized exclusively for the purpose of acquiring, holding and/or financing the acquisition of the securities of or other interest in one or more Nonutility Subsidiaries, provided that Intermediate Subsidiaries may also engage in Development Activities and Administrative Activities. To the extent such transactions are not exempt from the Act or otherwise authorized or permitted by rule, regulation or order of the Commission, PNM Resources requests authority for Intermediate Subsidiaries to engage in the Activities described above. To the extent that PNM Resources provides funds directly or indirectly to an Intermediate Subsidiary which are used for the purpose of making an investment in any Nonutility Subsidiary, the amount of such funds will be included in PNM Resources' ''aggregate investment'' in these entities, as calculated in accordance with rule 53 or rule 58, as applicable.

PNM Resources specifically requests authority to expend up to $300 million during the Authorization Period to acquire Energy Assets, within the United States and within Mexico, to the extent incidental to those United States operations and authorized under applicable import/export law. These acquisitions my also take the form of the acquisition of the securities of companies that exclusively engage in activities pertaining to the development or operation of the Energy Assets.

VII. Changes in Capital Stock of Subsidiaries

The portion of an individual subsidiary's aggregate financing to be effected through the sale of stock to PNM Resources during the Authorization Period pursuant to rule 52 and/or pursuant to an order issued in this proceeding cannot be ascertained at this time. It may happen that the proposed sale of capital securities may in some cases exceed the then-authorized capital stock of the subsidiary. In addition, the subsidiary may choose to use capital stock with no par value or receive a capital contribution without issuing capital stock. Also, a wholly-owned subsidiary may wish to engage in a reverse stock split to reduce franchise taxes. As needed to accommodate such proposed transactions and to provide for future issues, PNM Resources requests authority to change the terms of any such wholly-owned subsidiary's authorized capital stock capitalization by an amount deemed appropriate by PNM Resources or other intermediate parent company in the instant case. A subsidiary would be able to change the par value, or change between par value and no-par stock, without additional Commission approval. Any such action by a utility subsidiary would be subject to and would only be taken upon the receipt of any necessary approvals by the state commission(s) in the state or states in which such utility subsidiary is incorporated and doing business. PNM Resources states that in the event that proxy solicitations are necessary with respect to internal corporate reorganizations, PNM Resources will seek approval pursuant to sections 6(a)(2) and 12(e) of the Act, through the filing of an appropriate declaration.

VIII. Services Provided to Subsidiaries

PNM Resources intends to file with the Commission, no later than ninety (90) days after the Commission issues an order with respect to this Application, an application-declaration seeking authority to create a service company pursuant to rule 88 of the Act. Until the service company application is made effective, PNM Resources requests authorization under section 13(a) of the Act and Commission rules for PNM Resources to continue to provide support services on an interim basis to its subsidiaries through June 30, 2005. Currently, PNM Resources performs substantially all of the corporate activities of PNM. Charges for all services will be on an at-cost basis, as determined under rules 90 and 91 of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E4–3332 Filed 11–23–04; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50689; File No. SR–MSRB–2004–05]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Approving Proposed Rule Change To Offer New Historical Data Product

November 18, 2004.

On September 16, 2004, the Municipal Securities Rulemaking Board (''MSRB'' or ''Board''), filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to offer a new transparency product containing historical trade data obtained through the MSRB's Transaction Reporting System (the ''Historical Data Product''). The proposed rule change was published for comment in the **Federal Register** on October 18, 2004.[3] The Commission received no comments on the proposal.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the MSRB[4] and, in particular, the requirements of Section 15B(b)(2)(C) of the Act and the rules and regulations thereunder.[5] Section 15B(b)(2)(C) of the Act requires, among other things, that the MSRB's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 50491 (October 5, 2004), 69 FR 61422 (October 18, 2004) (''Notice'').

[4] In approving this rule the Commission notes that it has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[5] 15 U.S.C. 78o–4(b)(2)(C).

trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities, to remove impediments to and perfect the mechanism of a free and open market in municipal securities, and, in general, to protect investors and the public interest.

In particular, the Commission finds that the proposed rule change will increase transparency and facilitate the fair pricing of municipal securities transactions. The Commission believes that the Historical Data Product will provide more information on infrequently traded issues and will help achieve a wider dissemination of transaction information that will help ensure the fairest and most accurate pricing of municipal securities transactions.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[6] that the proposed rule change (SR–MSRB–2004–05) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E4–3308 Filed 11–23–04; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50692; File No. SR–MSRB–2004–07]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Municipal Securities Rulemaking Board To Establish Implementation Plan for Real-Time Transaction Reporting and Price Dissemination

November 18, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 15, 2004, the Municipal Securities Rulemaking Board (''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the MSRB. The MSRB has designated this proposal as constituting a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the MSRB under Section 19(b)(3)(A)(i) of the Act[3] and Rule 19b–4(f)(1) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB is filing with the Commission a proposal to establish the implementation plan for its real-time transaction reporting and price dissemination, which includes the amendments to Rule G–14, on transaction reporting, and Rule G–12(f), on automated comparison of inter-dealer transactions. No changes to the text of MSRB rules are required by this proposal.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposal. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 31, 2004, the SEC approved a proposed rule change relating to the MSRB's implementation of real-time transaction reporting and price dissemination—the Real-Time Transaction Reporting System or ''RTRS.''[5] That rule change includes amendments to Rule G–14 and Rule G–12(f), which will become effective concurrently with the operation of RTRS, that will require dealers to report most municipal securities transactions to the MSRB within 15 minutes of the time of trade execution rather than by midnight on trade date, as is currently required,[6] and to submit inter-dealer transactions to the central comparison system within the same time frame. The new requirements are designed to increase price transparency in the municipal securities market and to enhance the surveillance database and audit trail used by enforcement agencies.[7] In that filing, the MSRB stated that it expected to make a second filing on the RTRS facility in the future, stating the date of effectiveness, describing the technical means of data dissemination, and proposing fees to be charged for RTRS data products.

On October 25, 2004, the MSRB filed a proposal describing the proposed RTRS service for dissemination of real-time transaction price data (which is named the Real-Time Transaction Price Service) and proposed an annual subscription fee of $5,000.[8] That filing also described the fees, if any, associated with other RTRS data products. Thus, this proposal addresses the final remaining aspect of RTRS by establishing the implementation plan.

Implementation Plan

As announced in MSRB Notice 2003–44, dated December 11, 2003, the MSRB is implementing its real-time transaction reporting requirements for brokers, dealers and municipal securities dealers (collectively, ''dealers'') in January 2005. The implementation plan for the January transition is described below.

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[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(i).

[4] 17 CFR 240.19b–4(f)(1).

[5] Exchange Act Release No. 50294 (August 31, 2004), 69 FR 54170 (September 7, 2004); *see* ''Approval by the SEC of Real-Time Transaction Reporting and Price Dissemination: Rules G–12(f) and G–14,'' MSRB Notice 2004–29 (September 2, 2004), at *http://www.msrb.org.*

The text of the rule change, along with a description of the RTRS facility, can be found in the MSRB's notice announcing its filing with the SEC. *See* ''Real-Time Transaction Reporting: Notice of Filing of Proposed Rule Change to Rules G–14 and G–12(f),'' MSRB Notice 2004–13 (June 1, 2004), at *http://www.msrb.org.*

[6] For operational reasons, the rule will allow dealers more than 15 minutes to report certain kinds of transactions. These transactions still will be reported to subscribers immediately upon receipt at RTRS.

[7] The RTRS filing noted that certain trade reports made by dealers, which are coded by the dealers to indicate that the trade is for a specific reason not done at a market price, will not be disseminated but will be available to regulators as part of the surveillance function offered by RTRS. The RTRS Notice also noted that certain other types of ''transactions'' that are required to be reported exclusively for audit trail purposes (relating to clearing brokers and their correspondents in certain fully-disclosed clearing arrangements where the correspondent does not take a principal position) also will not be disseminated but will be available to regulators.

[8] File No. SR–MSRB–2004–06. *See* ''Notice of Filing to Create the Real-Time Transaction Price Service and Establish an Annual Subscription Fee,'' MSRB Notice 2004–35 (October 26, 2004), at *http://www.msrb.org.*

It should be noted that the transaction data will be available free-of-charge through The Bond Market Association's Web site at *http://www.investinginbonds.com*, as well as through other means.

The conversion to real-time transaction reporting requires dealers and the MSRB to implement new systems and procedures for transaction reporting. Trade reporting will be accomplished through a new MSRB system—the Real-Time Transaction Reporting System (''RTRS''). The two major components of RTRS with which dealers will interface are: (i) The RTRS Web Portal for inputting trade data and reviewing the status of trade reports within RTRS; and (ii) the message-based trade input and feedback facility operated by National Securities Clearing Corporation (the ''Message Portal''). These are described in the RTRS Operational Plan contained in MSRB Notice 2003–44 and in the RTRS Message Specifications and other explanatory documents subsequently published at *www.msrb.org*.

To facilitate a smooth transition to dealer use of the Web Portal and the Message Portal, implementation will occur in two phases on January 10 and January 31, 2005. Dealers will be required to incorporate use of the RTRS Web Portal into their transaction reporting procedures on January 10, on which date the MSRB also will convert its internal production processing and dealer-feedback systems to RTRS formats. Accomplishing this transition on January 10 will allow the MSRB and dealers to resolve any implementation issues associated with these system changes prior to the January 31 date for mandatory real-time trade reporting by all dealers. On January 31, the amendments to Rule G–12(f) and Rule G–14 that require real-time inter-dealer comparison and transaction reporting will become effective, use of the Message Portal will become mandatory, and the MSRB will begin real-time dissemination of trades in transparency reports.

Further details on the changes that will occur on January 10 and January 31 as part of the implementation plan are described below.

January 10, 2005—On this date, the MSRB will convert its own production system for processing transaction reports to RTRS. Dealers will not be required by rule to report in real-time on this date but will be encouraged to do so to ease the transition when real-time reporting becomes mandatory on January 31. On January 10, the RTRS database will become the ''database of record'' and dealers will need to employ the RTRS Web browser in their production environment. It should be noted that dealers that have tested successfully can already convert to real-time comparison and trade reporting procedures, although without all of the ''feedback'' functionally that will become available in the production environment on January 10. The MSRB's conversion to RTRS as the production processing system on January 10 will allow the MSRB to give these dealers full RTRS ''feedback'' capability on that date.

There will be no change in the timing of transparency reports on January 10. However, subscribers to the existing transparency reports can begin receiving T+1 reports in the RTRS revised record formats (including the new fields of trade information offered by RTRS) on that date. The following features of the existing transaction reporting system will be changed or terminated on January 10:

- The old ''batch'' style formats for reporting inter-dealer and customer trades through NSCC will still be accepted, but the deadline for reporting customer trades will be changed from midnight to 10:00 p.m. The deadline for inter-dealer trade reports will remain 8:00 p.m.
- Because of the MSRB's change to RTRS as the production processing system, dealers must use 16-digit (rather than 20-digit) control numbers to identify trades, both in real-time and in batch trade reports. Only 16-digit control numbers will be returned to dealers in message feedback.
- Regardless of whether a dealer is using the new RTRS formats or old batch style formats, the MSRB will discontinue sending ''feedback'' information in batch files and faxes for customer trades. Real-time system responses, e-mails and RTRS Web instead will be available to provide feedback to dealers on their trade reports.
- Dealers who submit their low-volume trade input through the current ''TRS dial-up'' facility must convert to the RTRS Web Portal by January 10.

January 31, 2005—On this date, the amendments to Rule G–14, on transaction reporting, and Rule G–12(f), on automated comparison of inter-dealer transactions, will become fully effective, requiring securities transactions to be reported, in most cases, within 15 minutes of the time of trade execution. Use of RTRS trade reporting formats and procedures will become mandatory and the old ''batch'' style reporting formats will no longer be compliant with Rules G–12(f) and G–14. (The MSRB will discontinue its support of the non-compliant trade reporting methodology soon after January 31.) The MSRB will make real-time transaction price data available to subscribers to its Real-Time Transaction Price Service beginning on this date.

2. Statutory Basis The MSRB has adopted the proposed rule change pursuant to Section 15B(b)(2)(C) of the Act,[9] which authorizes the MSRB to adopt rules that shall:

> be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities, to remove impediments to and perfect the mechanism of a free and open market in municipal securities, and, in general, to protect investors and the public interest.

The MSRB has a long-standing policy to increase price transparency in the municipal securities market, with the ultimate goal of disseminating comprehensive and contemporaneous pricing data. Since 1995, the MSRB has expanded the scope of its public transparency reports in several steps, and each step has provided industry participants and the public with more information about municipal securities transactions. This process has culminated in the RTRS system. The implementation plan establishes the date on which dealers will be required to report their municipal securities transactions to the MSRB in real-time and RTRS will formally begin operating. The MSRB encourages the redistribution of the data obtained through RTRS and believes that achieving the widest possible dissemination of transaction information will help ensure the fairest and most accurate pricing of municipal securities transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The MSRB does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The MSRB has designated this proposed rule change as constituting a stated policy, practice or interpretation with respect to the meaning, administration or enforcement of an existing MSRB rule under Section

[9] 15 U.S.C. 78o–4(b)(2)(C).

19(b)(3)(A)(i) of the Act,[10] and Rule 19b–4(f)(1) thereunder,[11] which renders the proposed rule change effective upon filing with the Commission.

At any time within 60 days of this filing, the Commission may summarily abrogate this proposal if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[12]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2004–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–MSRB–2004–07. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the office of the MSRB. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MSRB–2004–07 and should be submitted on or before December 15, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E4–3309 Filed 11–23–04; 8:45 am]

BILLING CODE 8010–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4.

[12] *See* 15 U.S.C. 78s(b)(3)(C).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50688; File No. PCAOB–2004–08]

Public Company Accounting Oversight Board; Order Approving Proposed Conforming Amendments to PCAOB Interim Standards Resulting From the Adoption of PCAOB Auditing Standard No. 2, ''An Audit of Internal Control Over Financial Reporting Performed in Conjunction With an Audit of Financial Statements''

November 17, 2004.

I. Introduction

On September 16, 2004, the Public Company Accounting Oversight Board (the ''Board'' or the ''PCAOB'') filed with the Commission proposed *Conforming Amendments to PCAOB Interim Standards Resulting From the Adoption of PCAOB Standard No. 2,* ''An Audit of Internal Control Over Financial Reporting Performed in Conjunction With an Audit of Financial Statements'' (''Conforming Amendments''), pursuant to the Sarbanes-Oxley Act of 2002 (the ''Act'')[1] and Section 19(b) of the Securities Exchange Act of 1934 (the ''Exchange Act''). The Conforming Amendments would change and add to the interim standards certain text, including references, to assist auditors in performing integrated audits of financial statements and internal control and would apply certain concepts developed in Auditing Standard No. 2 to assist an auditor engaged solely to audit the financial statements. Notice of the proposed Conforming Amendments was published in the **Federal Register** on October 13, 2004,[2] and the Commission received two comment letters. For the reasons discussed below, the Commission is granting approval of the proposed Conforming Amendments.

II. Description

The Act establishes the PCAOB to oversee the audits of public companies and related matters, to protect investors, and to further the public interest in the preparation of informative, accurate and independent audit reports.[3] Section 103(a) of the Act directs the PCAOB to establish auditing and related attestation standards, quality control standards, and ethics standards to be used by registered public accounting firms in the preparation and issuance of audit reports as required by the Act or the rules of the Commission. Section 103(a)(3) of the Act also states that the Board may adopt any statement of auditing or related professional practice standards developed by a professional group of accountants as interim or transitional standards, with the Board retaining full authority to modify, supplement, revise or subsequently amend, modify or repeal, in whole or in part, any such statements. Pursuant to this authority, the PCAOB adopted the auditing and related professional practice standards of the American Institute of Certified Public Accountants, as they existed on April 16, 2003, as interim or transitional standards (the ''interim standards'').[4]

The proposed Conforming Amendments specifically identify changes to the interim standards as a result of adopting PCAOB Auditing Standard No. 2. The identification of such changes is intended to help auditors comply with the Board's standards, as well as to eliminate potential confusion and inconsistencies in interpretation with respect to the affected portions of the Board's interim standards.

The Conforming Amendments also supersede AT Section 501, *Reporting on an Entity's Internal Control Over Financial Reporting* (''AT 501'')[5] and SAS No. 60, *Communication of Internal Control Related Matters Noted in an Audit* (''SAS No. 60'').[6] AT 501 provides guidance for performing an attestation engagement to issue an examination report on the effectiveness of an entity's internal control over financial reporting as of a point in time. The Board believes

[1] Sections 101, 103 and 107 of the Act.

[2] Release No. 34–50495 (October 5, 2004); 69 FR 60913 (October 13, 2004).

[3] Section 101(a) of the Act.

[4] The Commission approved the PCAOB's action in Release No. 34–47745, *Order Regarding Section 103(a)(3)(B) of the Sarbanes-Oxley Act of 2002,* (April 25, 2003).

[5] Statements on Standards for Attestation Engagements (''AT'') are codified into the AICPA *Professional Standards,* volume 1.

[6] Statements on Auditing Standards (''SAS'') are codified into the AICPA *Professional Standards,* volume 1.

that Auditing Standard No. 2 is a superior standard to its predecessor attestation standard, AT 501, and the proposal would supersede AT 501, effective immediately upon approval of the Conforming Amendments by the Commission. SAS No. 60 provides guidance in identifying and communicating conditions that relate to a company's internal control observed during an audit of the financial statements. SAS No. 60 for integrated audits (*i.e.*, audits of both financial statements and internal control over financial reporting) would be replaced by portions of Auditing Standard No. 2, and the proposal also would amend SAS 60 as it applies to financial statement only audits.

The proposed Conforming Amendments have multiple effective dates. The amendments that affect integrated audits for accelerated filers would be effective for fiscal years ending on or after November 15, 2004 (*i.e.*, at the same time as Auditing Standard No. 2 for integrated audits of accelerated filers that are subject to the Commission's rules implementing Section 404 [7] of the Act). Those amendments that affect audits of financial statements only and those that affect integrated audits of non-accelerated filers subject to the Commission's rules implementing Section 404 of the Act would be effective for fiscal years ending on or after July 15, 2005. Finally, the superseding of AT 501 would be effective immediately upon approval by the Commission.

III. Discussion

The Commission's comment period on the Proposed Standard ended on November 3, 2004, with the Commission receiving two comment letters. The comment letters came from two registered public accounting firms.

Both commenters expressed support for Commission approval of the Conforming Amendments.

IV. Conclusion

On the basis of the foregoing, the Commission finds that proposed Conforming Amendments are consistent with the requirements of the Act and the securities laws and are necessary and appropriate in the public interest and for the protection of investors.

It is therefore ordered, pursuant to Section 107 of the Act and Section 19(b)(2) of the Exchange Act, that the proposed *Conforming Amendments to PCAOB Interim Standards Resulting From the Adoption of PCAOB Standard No. 2*, ''An Audit of Internal Control Over Financial Reporting Performed in Conjunction With an Audit of Financial Statements'' (File No. PCAOB–2004–08), be and hereby are approved.

By the Commission.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. E4–3310 Filed 11–23–04; 8:45 am]

BILLING CODE 8010–01–P

[7] See Release No. 33–8238 (June 5, 2003) [68 FR 36636] and Release No. 33–8392 (February 24, 2004) [69 FR 9722].

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster # 3653]

State of Georgia

Charlton County and the contiguous counties of Brantley, Camden, and Ware in the State of Georgia; and Baker and Nassau Counties in the State of Florida constitute a disaster area as a result of damages caused by heavy rains and severe localized flooding from Tropical Storm Jeanne that occurred on September 25 and September 26, 2004. Applications for loans for physical damage as a result of the disaster may be filed until the close of business on January 18, 2005, and for economic injury until the close of business on August 16, 2005, at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	6.375
Homeowners Without Credit Available Elsewhere	3.187
Businesses With Credit Available Elsewhere	5.800
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	2.900
Others (Including Non-Profit Organizations) with Credit Available Elsewhere	4.875
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	2.900

The numbers assigned to this disaster for physical damage are 365306 for Georgia and 365406 for Florida. The numbers assigned to this disaster for economic injury are 9AJ800 for Georgia, and 9AJ900 for Florida.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: November 16, 2004.

Hector V. Barreto,

Administrator.

[FR Doc. 04–26015 Filed 11–23–04; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3652]

State of Hawaii

The city and county of Honolulu in the State of Hawaii constitutes a disaster area as a result of heavy rains and flooding that occurred on October 30, 2004 on the island of Oahu. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on January 18, 2005, and for economic injury until the close of business on August 16, 2005, at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 4 Office, P.O. Box 419004, Sacramento, CA 95841–9004.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.875
Homeowners Without Credit Available Elsewhere	2.937
Businesses With Credit Available Elsewhere	5.800
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) with Credit Available Elsewhere	4.750
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 365206 and for economic damage is 9AJ700.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: November 16, 2004.

Hector V. Barreto,

Administrator

[FR Doc. 04–26014 Filed 11–23–04; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster # 10001]

State of Maryland

Allegany County and the contiguous counties of Garrett and Washington in the State of Maryland; Bedford, Fulton,

and Somerset Counties in the Commonwealth of Pennsylvania; and Hampshire, Mineral, and Morgan Counties in the State of West Virginia constitute a disaster area as a result of heavy rains caused by the remnants of Hurricane Frances and Hurricane Ivan that occurred on September 6, 2004. Applications for loans for physical damage as a result of the disaster may be filed until the close of business on January 18, 2005, and for economic injury until the close of business on August 16, 2005, at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd., South 3rd Floor, Niagara Falls, NY 14303.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	6.375
Homeowners without credit available elsewhere	3.187
Businesses with credit available elsewhere	5.800
Businesses and non-profit organizations without credit available elsewhere	2.900
Others (including non-profit organizations) with credit available elsewhere	4.875
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	2.900

The number assigned to this disaster for physical damage is 10001 for Maryland, Pennsylvania, and West Virginia. The number assigned to this disaster for economic injury is 10002 for Maryland, Pennsylvania, and West Virginia.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: November 16, 2004.

Hector V. Barreto,

Administrator.

[FR Doc. 04–26016 Filed 11–23–04; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3650]

State of New York

As a result of the President's major disaster declaration for Public Assistance on October 1, 2004 and subsequent amendments adding Individual Assistance and establishing the incident period on November 16, 2004, I find that Allegany, Broome, Cattaraugus, Madison, Monroe, Niagara, Oneida, Onondaga, Orange, Orleans, Steuben, Sullivan, Ulster, and Wayne Counties in the State of New York constitute a disaster area due to damages caused by severe storms and flooding occurring on August 13, 2004 and continuing through September 16, 2004. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on January 18, 2005 and for economic injury until the close of business on August 16, 2005 at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd., South 3rd Fl., Niagara Falls, NY 14303–1192.

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Cayuga, Chautauqua, Chemung, Chenango, Columbia, Cortland, Delaware, Dutchess, Erie, Genesee, Greene, Herkimer, Lewis, Livingston, Ontario, Oswego, Otsego, Putnam, Rockland, Schuyler, Seneca, Tioga, Westchester, Wyoming, and Yates in the State of New York; Passaic and Sussex Counties in the State of New Jersey; and McKean, Pike, Potter, Susquehanna, Tioga, Warren, and Wayne Counties in the Commonwealth of Pennsylvania.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	6.375
Homeowners without credit available elsewhere	3.187
Businesses with credit available elsewhere	5.800
Businesses and non-profit organizations without credit available elsewhere	2.900
Others (including non-profit organizations) with credit available elsewhere	4.875
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	2.900

The number assigned to this disaster for physical damage is 365006. For economic injury the number is 9AJ500 for New York; 9AK100 for New Jersey; and 9AK200 for Pennsylvania.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: November 17, 2004.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 04–26013 Filed 11–23–04; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 4907]

Culturally Significant Objects Imported for Exhibition Determinations: ''In the Russian Tradition: A Historic Collection of 20th Century Russian Paintings''

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236 of October 19, 1999, as amended, and Delegation of Authority No. 257 of April 15, 2003 [68 FR 19875], I hereby determine that the objects to be included in the exhibition ''In the Russian Tradition: A Historic Collection of 20th Century Russian Paintings,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner. I also determine that the exhibition or display of the exhibit objects at the Smithsonian Institution S. Dillon Ripley Center International Gallery, Washington, DC, from on or about December 15, 2004, to on or about March 19, 2005; Museum of Russian Art, Minneapolis, MN, from on or about April 15, 2005, to on or about July 31, 2005, and at possible additional venues yet to be determined, is in the national interest. Public Notice of these Determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julianne Simpson, Attorney-Adviser, Office of the Legal Adviser, Department of State, (telephone: 202/619–6529). The address is Department of State, SA–44, 301 4th Street, SW., Room 700, Washington, DC 20547–0001.

Dated: November 19, 2004.

C. Miller Crouch,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 04–26170 Filed 11–23–04; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice 4903]

International Joint Commission Boundary Waters Treaty of 1909

The International Joint Commission (IJC) will hold public hearings on the report of its International Missisquoi Bay Task Force.

In May of this year, the Canadian and United States federal governments asked the IJC to review plans by the State of Vermont to modernize the Alburg-Swanton Bridge, involving the partial removal of the existing causeway, and to provide advice on whether the plans comply with Article IV of the Boundary Waters Treaty of 1909. Article IV states, in part, that ''boundary waters and waters flowing across the boundary shall not be polluted on either side to the injury of health or property on the other.''

In June, the IJC appointed an International Missisquoi Bay Task Force with members from the two federal governments, the state of Vermont and province of Quebec. IJC Commissioners and the Task Force held public consultation sessions in Saint-Georges-de-Clarenceville, Quebec and Swanton, Vermont in August. After reviewing the full range of available information, the Task Force reported to the IJC in October. Following the scheduled public hearings, the IJC will prepare its final report to the governments of the United States and Canada.

All interested organizations and citizens are invited to speak at the public hearings on the Task Force report to be held at the following times and locations:

Monday, December 6, 2004 from 7 p.m. to 9:30 p.m. at the Centre des Loisirs—1 rue Tourangeau in Saint-Georges-de-Clarenceville, Quebec.

Tuesday, December 7, 2004 from 7 p.m. to 9:30 p.m. at the Missiquoi Valley Union High School, 100 Thunderbird Drive, Swanton, Vermont.

As time will be limited, speakers are encouraged to highlight their comments at the public hearings and provide more detailed comments in writing. Written comments may also be sent to either address below for receipt by January 4, 2005:

Secretary, Canadian Section, 234 Laurier Avenue West, 22nd Floor, Ottawa, Ontario K1P 6K6, Fax: (613) 993–5583, Voice: (613) 995–2984, Email: *Commission@ottawa.ijc.org.*

Secretary, United States Section, 1250 23rd Street NW., Suite 100, Washington, DC 20440, Fax: (202) 467–0746, Voice: (202) 736–9024, Email: *Commission@washington.ijc.org.*

The International Joint Commission is an international organization established by the Boundary Waters Treaty of 1909. It assists the governments in managing waters along the border for the benefit of both countries in a variety of ways including examining issues referred to it by the two Federal governments.

More information, including the full text of the International Missisquoi Bay Task Force Report, may be found on the Commission's Web site, at *http://www.ijc.org.*

November 17, 2004.

James G. Chandler,

Acting Secretary, United States Section, Department of State.

[FR Doc. 04–26050 Filed 11–23–04; 8:45 am]

BILLING CODE 4710–14–P

DEPARTMENT OF STATE

[Public Notice 4891]

Industry Advisory Panel: Meeting Notice

The Industry Advisory Panel of the Overseas Buildings Operations will meet on Thursday, December 9, 2004 from 9:45 a.m. until 3:30 p.m. Eastern Standard Time. The meeting will be held at the Department of State, 2201 C Street, NW., (entrance on 23rd Street), Washington, DC. The majority of the meeting is devoted to an exchange of ideas between the Department's Bureau of Overseas Buildings Operations' senior management and the panel members, on design, operations and building maintenance. Members of the public are asked to kindly refrain from joining the discussion until Director Williams opens the discussion to the public.

Due to limited seating space for members of the public, we ask that you kindly e-mail your information. To participate in this meeting, simply register by e-mail at *IAPR@STATE.GOV* before December 3, 2004. Your email should include the following information; Date of birth, social security number, company name and title. This information is required to issue a temporary pass to enter the building.

For questions, please contact *PinzinoLE3@state.gov* or call tel: 703/875–6872; Ms. Gina Pinzino; or *SpragueMA@state.gov* tel: 703/875–7173 for Michael Sprague.

Charles E. Williams,

Director/Chief Operating Officer, Overseas Buildings Operations, Department of State.

[FR Doc. 04–26169 Filed 11–23–04; 8:45 am]

BILLING CODE 4710–24–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Public Comment With Respect to the Annual National Trade Estimate Report on Foreign Trade Barriers

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: Pursuant to section 303 of the Trade and Tariff Act of 1984, as amended, USTR is required to publish annually the National Trade Estimate Report on Foreign Trade Barriers (NTE). With this notice, the Trade Policy Staff Committee (TPSC) is requesting interested parties to assist it in identifying significant barriers to U.S. exports of goods, services and overseas direct investment for inclusion in the NTE. Particularly important are impediments materially affecting the actual and potential financial performance of an industry sector. The TPSC invites written comments that provide views relevant to the issues to be examined in preparing the NTE. In order to ensure the most timely processing of submissions, the Department of Commerce will receive comments in response to this Notice.

DATES: Public comments are due not later than Tuesday, December 21, 2004. This deadline is firm. No submissions will be accepted after December 21.

ADDRESSES: *Paper submissions:* NTE Comments, U.S. Department of Commerce, USA Trade Center Room, 14th & Constitution Ave., NW., Ronald Reagan Building, Washington, DC 20230.

Submissions by electronic mail: *ntecomments@ita.doc.gov.*

FOR FURTHER INFORMATION CONTACT: Procedural questions about transmitting comments or viewing public submissions should be directed to Mrs. Lisa Leyser on (202–482–3433), U.S. Department of Commerce. Questions regarding the report or its subject matter should be directed to Ms. Gloria Blue, Office of Policy Coordination, Office of the United States Trade Representative (202–395–3475).

SUPPLEMENTARY INFORMATION: Last year's report may be found on USTR's Internet Home Page *(http://www.ustr.gov)* under the section on Reports. In order to ensure compliance with the statutory mandate for reporting foreign trade barriers that are significant, we will focus particularly on those restrictions where there has been active private sector interest.

The information submitted should relate to one or more of the following ten categories of foreign trade barriers:

(1) Import policies (*e.g.*, tariffs and other import charges, quantitative restrictions, import licensing, and customs barriers);

(2) Standards, testing, labeling, and certification (including unnecessarily restrictive application of phytosanitary standards, refusal to accept U.S. manufacturers' self-certification of conformance to foreign product standards, and environmental restrictions);

(3) Government procurement (*e.g.*, ''buy national'' policies and closed bidding);

(4) Export subsidies (*e.g.*, export financing on preferential terms and agricultural export subsidies that displace U.S. exports in third country markets);

(5) Lack of intellectual property protection (*e.g.*, inadequate patent, copyright, and trademark regimes);

(6) Services barriers (*e.g.*, limits on the range of financial services offered by foreign financial institutions, regulation of international data flows, restrictions on the use of data processing, quotas on imports of foreign films, and barriers to the provision of services by professionals (*e.g.*, lawyers, doctors, accountants, engineers, nurses, etc.);

(7) Investment barriers (*e.g.*, limitations on foreign equity participation and on access to foreign government-funded R&D consortia, local content, technology transfer and export performance requirements, and restrictions on repatriation of earnings, capital, fees and royalties);

(8) Anticompetitive practices with trade effects tolerated by foreign governments (including anticompetitive activities of both state-owned and private firms that apply to services or to goods and that restrict the sale of U.S. products to any firm, not just to foreign firms that perpetuate the practices);

(9) Trade restrictions affecting electronic commerce (*e.g.*, tariff and non-tariff measures, burdensome and discriminatory regulations and standards, and discriminatory taxation); and

(10) Other barriers (*i.e.*, barriers that encompass more than one category, *e.g.*, bribery and corruption, or that affect a single sector).

As in the case of last year's NTE, we are asking that particular emphasis be placed on any practices that may violate U.S. trade agreements. We are also interested in receiving any new or updated information pertinent to the barriers covered in last year's report as well as new information. Please note that the information not used in the NTE will be maintained for use in future negotiations.

It is most important that your submission contain estimates of the potential increase in exports that would result from the removal of the barrier, as well as a clear discussion of the method(s) by which the estimates were computed. Estimates should fall within the following value ranges: Less than $5 million; $5 to $25 million; $25 million to $50 million; $50 million to $100 million; $100 million to $500 million; or over $500 million. Such assessments enhance USTR's ability to conduct meaningful comparative analyses of a barrier's effect over a range of industries.

Please note that interested parties discussing barriers in more than one country should provide a separate submission (*i.e.*, one that is self-contained) for each country.

Written Comments: In order to ensure the most timely receipt and consideration of comments submitted in response to this Notice, the following guidelines and special procedures have been established:

(1) All comments will be received at the U.S. Department of Commerce rather than the Office of the United States Trade Representative;

(2) The Department of Commerce has arranged to accept non-confidential, public submissions by electronic mail (e-mail). An automatic reply confirming receipt of e-mail submissions will be sent. E-mail submissions in Microsoft Word or Corel WordPerfect are preferred. If a word processing application other than those two is used, please advise us in your submission of the specific application used;

(3) In order to facilitate prompt processing of submissions, the Department of Commerce strongly urges and prefers e-mail submission of non-confidential, public comments;

(4) To ensure security, submissions containing business confidential information should not be sent by e-mail, but via the U.S. Postal Service or commercial express delivery (see paragraph 6 and 7 below for special requirements applying to such submissions). If a submission contains business confidential information, a non-confidential public version must also be submitted along with the business confidential version.

(5) Business-confidential submissions must be accompanied by a justification as to why the information contained in the submission should be treated confidentially. In addition, any submissions containing business confidential information must be clearly marked ''Confidential'' at the top and bottom of the cover page (or letter) and of each succeeding page of the submission.

The version that does not contain confidential information should also be clearly marked, at the top and bottom of each page, ''public version'' or ''non-confidential''.

(6) When comments are submitted using the U.S. Postal Service or commercial couriers, it is strongly recommended that submitters notify the Department of Commerce by e-mail (*ntecomments@ita.doc.gov*) as to the date of transmittal and method of delivery (U.S. Postal Service or name of courier company).

(7) All submissions must be in English and should conform to the information requirements of 15 CFR 2003. If submissions are made via U.S. Postal Service or commercial express delivery, the submission should be accompanied by a computer disk containing a machine-readable version. The disk should have a label identifying the software used, the submitter and the title of the submission. In addition, business confidential and public or non-confidential submissions should be submitted on separate disks which are clearly marked ''business confidential'' or ''non-confidential'', as appropriate.

Submissions must be received at the Department of Commerce no later than Tuesday, December 21, 2004.

After the filing deadline, arrangements can be made to view these non-proprietary public comments at the U.S. Department of Commerce's USA Trade Center, in the Trade Reference Library. The USA Trade Center is located in the Ronald Reagan Building, Suite 800 on the Mezzanine Level, at 1300 Pennsylvania Ave., NW., Washington, DC 20004. The Trade Reference Library is open from 8:30 a.m. to 5 p.m., Monday through Friday. Call 202–482–0200 to confirm. Questions regarding the operation of the library should be directed to Mrs. Lisa Leyser at 202–482–3433.

Carmen Suro-Bredie,

Chair, Trade Policy Staff Committee.

[FR Doc. 04–26034 Filed 11–23–04; 8:45 am]

BILLING CODE 3190–W5–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments Concerning Compliance with Telecommunications Trade Agreements

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of request for public comment and reply comment.

SUMMARY: Pursuant to section 1377 of the Omnibus Trade and Competitiveness Act of 1988 (19 U.S.C. 3106) (''section 1377''), the Office of the United States Trade Representative (''USTR'') is reviewing, and requests comments on: the operation and effectiveness of and the implementation of and compliance with the World Trade Organization (''WTO'') Basic Telecommunications Agreement; other WTO agreements affecting market opportunities for telecommunications products and services of the United States; the telecommunications provisions of the North American Free Trade Agreement (''NAFTA''); the Chile and Singapore Free Trade Agreements (FTA) and any other FTAs coming into force on or before January 1, 2005; and other telecommunications trade agreements. The USTR will conclude the review by March 31, 2005.

DATES: Comments are due by noon on December 17, 2004 and Reply Comments are due by noon on January 17, 2005.

ADDRESSES: Gloria Blue, Executive Secretary, Trade Policy Staff Committee, ATTN: Section 1377 Comments, Office of the United States Trade Representative, 1724 F Street, NW., Washington, DC 20508.

FOR FURTHER INFORMATION CONTACT: Kenneth Schagrin, Office of Industry and Telecommunications (202) 395–5663; or Jim Kelleher, Office of the General Counsel (202) 395–3858.

SUPPLEMENTARY INFORMATION: Section 1377 requires the USTR to review annually the operation and effectiveness of all U.S. trade agreements regarding telecommunications products and services of the United States that are in force with respect to the United States. The purpose of the review is to determine whether any act, policy, or practice of a country that has entered into a telecommunications trade agreement with the United States is inconsistent with the terms of such agreement, or otherwise denies to U.S. firms, within the context of the terms of such agreements, mutually advantageous market opportunities. For the current review, the USTR seeks comments on:

(1) Whether any WTO member is acting in a manner that is inconsistent with its commitments under the WTO Basic Telecommunications Agreement or with other WTO obligations, e.g., the WTO General Agreement on Trade in Services (''GATS''), including the Annex on Telecommunications and the Reference Paper on Pro-Competitive Regulatory Principles, that affect market opportunities for U.S. telecommunications products and services;

(2) Whether Canada or Mexico has failed to comply with their telecommunications commitments or obligations under NAFTA;

(3) Whether Chile or Singapore or any other FTA partner with an Agreement that comes into force on or before January 1, 2005 has failed to comply with their telecommunications commitments or obligations under the respective FTAs between the United States and those countries;

(4) Whether other countries have failed to comply with their commitments under additional telecommunications agreements with the United States, *e.g.*, Mutual Recognition Agreements (MRAs) for Conformity Assessment of Telecommunications Equipment. A collection of all trade agreements, including ones related to telecommunications, can be found at *http://www.tcc.mac.doc.gov*.

(5) Whether there remain outstanding issues from previous Section 1377 reviews on those countries or issues previously cited. Last year's review can be found at *http://www.ustr.gov/Trade_Sectors/Manufacturing/Telecom/Section_Index.html*.

Public Comment and Reply Comment: Requirements For Submissions

All comments must be in English, identify on the first page of the comments the telecommunications trade agreement(s) discussed therein, and be submitted by noon on December 17, 2004. Reply Comments must be submitted by noon on January 17, 2005. Reply comments should only address issues raised by the comments.

In order to ensure the most timely and expeditious receipt and consideration of comments and reply comments, USTR has arranged to accept submissions in electronic format (e-mail). Comments should be submitted electronically to *FR0502@USTR.EOP.GOV*. An automatic reply confirming receipt of e-mail submission will be sent. E-mail submissions in Microsoft Word or Corel WordPerfect are preferred. If a word processing application other than those two is used, please include in your submission the specific application used. For any document containing business confidential information submitted electronically, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. Filers must also submit a public version of their comments. The file name of the public version should begin with the character ''P.'' The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments or reply comments. Interested persons who make submissions electronically should not provide separate cover letters; rather, information that might appear in a cover letter should be included in the submission itself. Similarly, to the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files. All non-confidential comments and reply comments will be placed on the USTR Web site, *http://www.USTR.gov* and in the USTR Reading Room for inspection shortly after the filing deadline, except business confidential information exempt from public inspection in accordance with 15 CFR 2003.6.

We strongly urge people to avail themselves of the electronic filing, if at all possible. If an e-mail submission is impossible, 15 copies of both the business confidential and public versions must be delivered via private commercial courier, and arrangements must be made with Ms. Blue prior to delivery for their receipt. Ms. Blue should be contacted at (202) 395–3475. Since comments and reply comments will be posted on USTR's Web site, those persons not availing themselves of electronic filing must submit their 15 copies with a diskette.

An appointment to review the comments may be made by calling the USTR Reading Room at (202) 395–6186. The USTR Reading Room is open to the public from 9:30 a.m. to 12 noon, and from 1 p.m. to 4 p.m., Monday through Friday, and is located in Room 3 of 1724 F Street., NW.

Carmen Suro-Bredie,

Chairman, Trade Policy Staff Committee.

[FR Doc. 04–26033 Filed 11–23–04; 8:45 am]

BILLING CODE 3190–W4–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34554 (Sub-No. 1)]

Union Pacific Railroad Company—Temporary Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway Company

AGENCY: Surface Transportation Board.

ACTION: Partial revocation of exemption.

SUMMARY: The Board, under 49 U.S.C. 10502, revokes the class exemption as it pertains to the trackage rights described in STB Finance Docket No. 34554 to permit the trackage rights to expire on or about December 31, 2004, in accordance with the agreement of the parties,[1] subject to the employee protective conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

DATES: This exemption will be effective on December 24, 2004. Petitions to stay must be filed by December 6, 2004. Petitions to reopen must be filed by December 14, 2004.

ADDRESSES: An original and 10 copies of all pleadings referring to STB Finance Docket No. 34554 (Sub-No.1) must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of all pleadings must be served on petitioner's representative: Robert T. Opal, 1400 Douglas Street, STOP 1580, Omaha, NE 68179.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 565–1609. [Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: ASAP Document Solutions, 9332 Annapolis Rd., Suite 103, Lanham, MD 20706. Telephone: (202) 306–4004. [Assistance for the hearing impaired is available through FIRS at 1–800–877–8339.]

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: November 17, 2004.

By the Board, Chairman Nober, Vice Chairman Mulvey, and Commissioner Buttrey.

Vernon A. Williams,

Secretary.

[FR Doc. 04–25932 Filed 11–23–04; 8:45 am]

BILLING CODE 4915–01–P

[1] On September 17, 2004, the Union Pacific Railroad Company (UP) concurrently filed a verified notice of exemption under the Board's class exemption procedures at 49 CFR 1180.2(d)(7). The notice covered the agreement by The Burlington Northern and Santa Fe Railway Company (BNSF) to grant temporary local trackage rights to UP over a BNSF line of railroad between BNSF milepost 579.3 near Mill Creek, OK, and BNSF milepost 631.1 near Joe Junction, TX, a distance of approximately 51 miles. UP submits that the trackage rights are only temporary rights, but, because they are ''local'' rather than ''overhead'' rights, they do not qualify for the Board's class exemption for temporary trackage rights at 49 CFR 1180.2(d)(8). *See Union Pacific Railroad Company—Temporary Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway Company,* STB Finance Docket No. 34554 (STB served Oct. 7, 2004). The trackage rights operations under the exemption were scheduled to begin on September 24, 2004.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34604]

Rio Valley Railroad, Inc.—Acquisition Exemption—Rail Lines of Union Pacific Railroad Company in Cameron County, TX

Rio Valley Railroad, Inc. (RVRI), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire by lease approximately 17.38 miles of rail lines located in Cameron County, TX, from the Union Pacific Railroad Company (UP). RVRI will lease the following rail lines: (1) A portion of the Mission Industrial Lead from milepost 0.06, at a point 50 feet measured at a right angle from UP's Brownsville Subdivision main track No. 104 at Harlingen, TX, to milepost 1.00 in Harlingen Yard at Harlingen, TX; (2) the Santa Rosa Industrial Lead from milepost 0.00 in Harlingen Yard at Harlingen, TX, to milepost 11.38 near Rogers Lacy, TX; and (3) approximately 5 miles of track in Harlingen Yard at Harlingen, TX.

This transaction is related to STB Finance Docket No. 34605, *Rio Valley Switching Company—Operation Exemption—Rio Valley Railroad, Inc.,* wherein Rio Valley Switching Company seeks to operate the lines being leased by RVRI.

RVRI certifies that its projected revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier. The transaction was scheduled to be consummated no sooner than November 2, 2004, the effective date of the exemption (7 days after the exemption was filed).

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34604, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Thomas F. McFarland, Thomas F. McFarland, P.C., 208 South LaSalle Street, #1890, Chicago, IL 60604–1112.

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov.*''

Decided: November 17, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–26054 Filed 11–23–04; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34605]

Rio Valley Switching Company—Operation Exemption—Rio Valley Railroad, Inc.

Rio Valley Switching Company (RVSC), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to operate, pursuant to an agreement with Rio Valley Railroad, Inc. (RVRI), approximately 17.38 miles of rail lines owned by the Union Pacific Railroad Company (UP) located in Cameron County, TX, consisting of: (1) A portion of the Mission Industrial Lead from milepost 0.06, at a point 50 feet measured at a right angle from UP's Brownsville Subdivision main track No. 104 at Harlingen, TX, to milepost 1.00 in Harlingen Yard at Harlingen, TX; (2) the Santa Rosa Industrial Lead from milepost 0.00 in Harlingen Yard at Harlingen, TX, to milepost 11.38 near Rogers Lacy, TX; and (3) approximately 5 miles of track in Harlingen Yard at Harlingen, TX.

This transaction is related to STB Finance Docket No. 34604, *Rio Valley Railroad, Inc.—Acquisition Exemption—Rail Lines of Union Pacific Railroad Company in Cameron County, TX,* wherein RVRI seeks to acquire by lease, the lines to be operated by RVSC.

RVSC certifies that its projected revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier. The transaction was scheduled to be consummated no sooner than November 2, 2004, the effective date of the exemption (7 days after the exemption was filed).

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34605, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Thomas F. McFarland, Thomas F. McFarland, P.C., 208 South LaSalle Street, #1890, Chicago, IL 60604–1112.

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov.*''

Decided: November 17, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–26055 Filed 11–23–04; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Departmental Offices; Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on an information collection that is due for revision approval by the Office of Management and Budget. The Office of International Affairs within the Department of the Treasury is soliciting comments concerning the collection of data for the Annual Report of Foreign Residents' Holdings of U.S. Securities, including Selected Money Market Instruments. The next such collection is to be conducted as of June 30, 2005.

DATES: Written comments should be received on or before January 24, 2005, to be assured of consideration.

ADDRESSES: Direct all written comments to Dwight Wolkow, International Portfolio Investment Data Systems, Department of the Treasury, Room 4410–1440NYA, 1500 Pennsylvania Avenue NW., Washington DC 20220. In view of possible delays in mail delivery, you may also wish to send a copy to Mr. Wolkow by e-mail (*dwight.wolkow@do.treas.gov*) or FAX (202–622–1207). Mr. Wolkow can also be reached by telephone (202–622–1276).

FOR FURTHER INFORMATION CONTACT: Copies of the proposed forms and instructions are available in Part II on the Treasury's TIC Forms webpage, *http://www.treas.gov/tic/forms.html.* Requests for additional information should be directed to Mr. Wolkow.

SUPPLEMENTARY INFORMATION:

Title: Treasury Department Form SHLA/SHL, Foreign-Residents' Holdings of U.S. Securities, including Selected Money Market Instruments.

OMB Number: 1505–0123.

Abstract: These forms are used to conduct annual surveys of holdings by foreign-residents of U.S. securities for portfolio investment purposes. These data are used by the U.S. Government in the formulation of international and financial policies and for the computation of the U.S. balance of payments accounts and the U.S. international investment position. These data will also be used to provide information to the public and to meet international reporting commitments.

The benchmark survey (Form SHL) is conducted once every five years, and requires reporting by all significant U.S.-resident custodians and U.S.-resident security issuers. In non-benchmark years an annual survey (Form SHLA) is conducted, and requires reports from only the very largest U.S.-resident custodians and issuers. The data requested will be the same in Form SHL and, during the four succeeding years, in Form SHLA. The determination of who must report in the annual surveys (SHLA) will be based upon the securities data submitted during the previous benchmark survey. The data collected under the annual surveys (SHLA) will be used in conjunction with the results of the previous benchmark survey to compute economy-wide estimates for the non-benchmark years.

Current Actions: (a) On Schedule 1, added new ''Item 15—Valuation Technique''. This information is very helpful for understanding and utilizing the data reported. (b) On Schedule 2, item 11 (Registered/Bearer) will not be used. (Note that the reporting requirements for registered and bearer securities do not change). (c) On Schedule 2, item 17 (Reason for Zero) will not be used. While both items 11 and 17 will not be used, in order to reduce reporting burden, they will be on the form as ''Intentionally Left Blank'' to limit computer programming changes. (d) On Schedule 2, added a third option of ''Individual'' to item 15 (Type of Foreign Holder). Reporters now will have three options for type of foreign holder 1. Official, 2. Individual, 3. Other. (e) Clarified the instructions for certain sections, most notably the ''Securities involved in lending arrangements'' section and the section that deals with what determines foreign residency. (f) Added two country codes for Mayotte (under Africa) and Wallis and Futuna (under Other Countries).

Type of Review: Revision of a currently approved data collection.

Affected Public: Business/financial institutions.

Forms: TDF SHLA, Schedule 1 and Schedule 2 (1505–0123); TDF SHL, Schedule 1 and Schedule 2 (1505–0123).

Estimated Number of Respondents: an annual average (over five years) of 360, but this varies widely from about 1,500 in benchmark years (once every five years) to about 65 in each of the other years (four out of every five years).

Estimated Average Time per Respondent: an annual average (over five years) of about 85 hours, but this will vary widely from respondent to respondent. (a) In the year of a benchmark survey, which is conducted once every five years, it is estimated that exempt respondents will require an average of 16 hours; for custodians of securities, the estimate is a total of 321 hours on average, but this figure will vary widely for individual custodians; and for issuers of securities that have data to report and are not custodians, the estimate is 61 hours on average. (b) In a non-benchmark year, which occurs four years out of every five years: for the largest custodians of securities, the estimate is a total of 486 hours on average; and for the largest issuers of securities that have data to report and are not custodians, the estimate is 110 hours on average.

Estimated Total Annual Burden Hours: an annual average (over five years) of 30,600 hours.

Frequency of Response: Annual.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit written comments concerning: (a) whether the Survey is necessary for the proper performance of the functions of the Office, including whether the information collected has practical uses;

(b) the accuracy of the above burden estimates; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or recordkeeping burdens on respondents, including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchases of services to provide information.

Dwight Wolkow,

Administrator, International Portfolio Investment Data Systems.

[FR Doc. 04–26009 Filed 11–23–04; 8:45 am]

BILLING CODE 4810–25–P

Federal Register

Wednesday,
November 24, 2004

Part II

Environmental Protection Agency

40 CFR Parts 9, 122 et al.

National Pollutant Discharge Elimination System—Proposed Regulations To Establish Requirements for Cooling Water Intake Structures at Phase III Facilities; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 122, 123, 124, and 125

[OW–2004–0002, FRL–7834–7]

RIN 2040–AD70

National Pollutant Discharge Elimination System—Proposed Regulations To Establish Requirements for Cooling Water Intake Structures at Phase III Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Today's proposed rule would establish national categorical requirements under section 316(b) of the Clean Water Act for certain existing facilities that employ a cooling water intake structure and are designed to withdraw water above a certain design intake flow from certain waters of the United States for cooling purposes. Today's notice proposes three possible options for defining which existing facilities would be subject to uniform national requirements, based on design intake flow threshold and source waterbody type: The facility has a total design intake flow of 50 million gallons per day (MGD) or more, and withdraws from any waterbody; the facility has a total design intake flow of 200 MGD or more, and withdraws from any waterbody; or the facility has a total design intake flow of 100 MGD or more and withdraws water specifically from an ocean, estuary, tidal river, or one of the Great Lakes. Because the lowest co-proposed flow threshold option is 50 MGD, the proposed requirements would only apply to manufacturing facilities—as power producers with a flow greater than 50 MGD are regulated under the Phase II rule. This proposed rule would constitute Phase III of EPA's section 316(b) regulation development and would establish national requirements, and procedures for implementing those requirements, applicable to the location, design, construction, and capacity of cooling water intake structures at Phase III facilities. Today's proposed rule would also establish categorical section 316(b) requirements for new offshore oil and gas extraction facilities, which were specifically excluded from the scope of the Phase I new facility rule so that EPA could gather additional data on these facilities. The proposed rule would apply to both existing manufacturers and new offshore oil and gas extraction facilities that withdraw at least 25 percent of the water exclusively for cooling purposes.

The proposed national requirements, which would be implemented through National Pollutant Discharge Elimination System (NPDES) permits, are based on the best technology available to minimize the adverse environmental impact associated with the use of cooling water intake structures. For covered existing facilities, today's proposed rule would establish performance standards for reducing impingement mortality by 80 to 95 percent, or impingement mortality by 80 to 95 percent and entrainment by 60 to 90 percent. Today's proposal would allow existing facilities to select from five compliance alternatives consistent with those provided in the final Phase II rule for existing large flow electric power generators. Once finalized and implemented, the rule would minimize the adverse environmental impact of cooling water intake structures by reducing the number of aquatic organisms lost as a result of water withdrawals associated with these structures.

Today's proposed rule does not propose to alter the regulatory requirements for facilities subject to the Phase I or Phase II regulations, and EPA is not soliciting comment on those regulations. EPA is only seeking comment on the proposed regulations for Phase III existing facilities and new offshore oil and gas facilities, as reflected in the proposed regulatory text for subparts K and N. Depending on the options selected in the final section 316(b) regulation for Phase III facilities, EPA may decide to integrate the regulatory text for subparts K and N proposed today into the existing subparts I and J, for purposes of streamlining the number of pages for publication.

DATES: Comments must be received on or before March 24, 2005.

ADDRESSES: Submit your comments, identified by Docket ID No. OW–2004–0002, by one of the following methods:

I. Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

II. Agency Web site: *http://www.epa.gov/edocket*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

III. E-mail: *OW–Docket@epa.gov*.

IV. Mail: Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OW–2004–0002. Please include a total of 3 copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.

V. Hand Delivery: Water Docket, EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OW–2004–0002. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. OW–2004–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102). For additional instructions on submitting comments, go to section B of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other

information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Water Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: For additional technical information contact Martha Segall at (202) 566–1041 or Paul Shriner at (202) 566–1076. For economic information, contact Erik Helm at (202) 566–1066. For biological information contact Ashley Allen at (202) 566–1012. The address for the above contacts is: Office of Science and Technology, Engineering Analysis Division (Mailcode 4303T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; fax number: (202) 566–1053; e-mail address: *rule.316b@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

A. What Entities Are Regulated by This Action?

This proposed rule would apply to ''Phase III existing facilities''—*i.e.*, certain existing manufacturing and industrial facilities that are: (1) Point sources; (2) use or propose to use one or more cooling water intake structures; (3) are designed to withdraw water above a certain threshold from certain waters of the U.S. (the flow threshold would differ depending on the regulatory option selected in the final rule); and (4) use at least 25 percent of water withdrawn exclusively for cooling purposes. Depending on the regulatory option selected, the facility would be subject to these national requirements if it had a design intake flow of: (1) 50 MGD or more from any waterbody; (2) 200 MGD or more from any waterbody; or (3) 100 MGD or more from an ocean, estuary, tidal river, or one of the Great Lakes. This proposed rule would define ''existing facility'' as any manufacturing or industrial facility that commenced construction on or before January 17, 2002 (or [60 days from publication of the final rule] for an offshore oil and gas extraction facility), and any modification of, or any addition of a unit at such a facility that does not meet the definition of a new facility at § 125.83.

This proposed rule would also apply to new offshore and coastal oil and gas extraction facilities, which were specifically excluded from the Phase I new facility rule. An offshore and coastal oil and gas extraction facility is new if construction commenced after 60 days from publication of the final rule. Exhibit 1 provides examples of industrial facility types potentially regulated by this proposed rule.

EXHIBIT 1.—EXAMPLES OF INDUSTRIAL FACILITY TYPES POTENTIALLY REGULATED BY THIS PROPOSED RULE

Category	Examples of potentially regulated entities	Standard industrial classification codes	North American industry codes (NAIC)
Federal, State and local government.	Operators of steam electric generating point source dischargers that employ cooling water intake structures.	4911 and 493	221111, 221112, 221113, 221119, 221121, 221122
Industry	Operators of industrial point source dischargers that employ cooling water intake structures..	See below	See below
	Agricultural production	0133	111991, 11193
	Metal mining	1011	21221
	Oil and gas extraction	1311, 1321	211111, 211112
	Mining and quarrying of nonmetallic minerals	1474	212391
	Food and kindred products	2046, 2061, 2062, 2063, 2075, 2085.	311221, 311311, 311312, 311313, 311222, 311225, 31214
	Tobacco products	2141	312229, 31221
	Textile mill products	2211	31321
	Lumber and wood products, except furniture	2415, 2421, 2436, 2493	321912,321113, 321918, 321999, 321212, 321219
	Paper and allied products	2611, 2621, 2631, 2676	3221, 322121, 32213, 322121, 322122, 32213, 322291
	Chemical and allied products	28 (except 2895, 2893, 2851, and 2879).	325 (except 325182, 32591, 32551, 32532)
	Petroleum refining and related industries	2911, 2999	32411, 324199
	Rubber and miscellaneous plastics products	3011, 3069	326211, 31332, 326192, 326299
	Stone, clay, glass, and concrete products	3241	32731
	Primary metal industries	3312, 3313, 3315, 3316, 3317, 3334, 3339, 3353, 3363, 3365, 3366.	324199, 331111, 331112, 331492, 331222, 332618, 331221, 22121, 331312, 331419, 331315, 331521, 331524, 331525
	Fabricated metal products, except machinery and transportation equipment.	3421, 3499	332211, 337215, 332117, 332439, 33251, 332919, 339914, 332999
	Industrial and commercial machinery and computer equipment.	3523, 3531	333111, 332323, 332212, 333922, 22651, 333923, 33312
	Transportation equipment	3724, 3743, 3764	336412, 333911, 33651, 336416

EXHIBIT 1.—EXAMPLES OF INDUSTRIAL FACILITY TYPES POTENTIALLY REGULATED BY THIS PROPOSED RULE—Continued

Category	Examples of potentially regulated entities	Standard industrial classification codes	North American industry codes (NAIC)
	Measuring, analyzing, and controlling instruments; photographic, medical, and optical goods; watches and clocks.	3861	333315, 325992
	Electric, gas, and sanitary services	4911, 4931, 4939, 4961	221111, 221112, 221113, 221119, 221121, 221122, 22121, 22133
	Educational services	8221	61131
	Engineering, accounting, research, management and related services.	8731	54171

This exhibit is not intended to be exhaustive, but rather provides a guide for readers regarding entities that may be regulated by this action if they satisfy the final flow threshold and waterbody type criteria. This exhibit lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the exhibit could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in § 125.101 and § 125.131 of this proposal. If you have questions regarding the applicability of this action to a particular entity, consult the persons listed for technical information in the **FOR FURTHER INFORMATION CONTACT** section.

B. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting Confidential Business Information (CBI). Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send information claimed as CBI by mail only to the following address, Office of Science and Technology, Mailcode 4303T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention: Ahmar Siddiqui /Docket ID No. OW–2004–0002. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

2. Tips for Preparing Your Comments. When submitting comments, remember to:

I. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

II. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

III. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

IV. Describe any assumptions and provide any technical information and/or data that you used.

IV. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

V. Provide specific examples to illustrate your concerns, and suggest alternatives.

VI. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

VII. Make sure to submit your comments by the comment period deadline identified.

C. Supporting Documentation

The proposed regulation is supported by three major documents:

1. Economic Analysis for the Proposed Section 316(b) Rule for Phase III Facilities (EPA–821–R–04–016), hereafter referred to as the Economic Analysis (EA). This document presents the analysis of compliance costs, closures, energy supply effects, and benefits associated with the final rule.

2. Regional Benefits Assessment for the Proposed Section 316(b) Rule for Phase III Facilities (EPA–821–R–04–017), hereafter referred to as the Regional Analysis Document or the Regional Study(ies) Document. This document examines cooling water intake structure impacts and regulatory benefits at the regional level.

3. Technical Development Document for the Proposed Section 316(b) Rule for Phase III Facilities (EPA–821–R–04–015), hereafter referred to as the Technical Development Document. This document presents detailed information on the methods used to develop unit costs and describes the set of technologies that may be used to meet the final rule's requirements.

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I. Legal Authority, Purpose, and Background of Today's Regulation

A. Legal Authority

Today's proposed rule is issued under the authority of sections 101, 301, 304, 306, 308, 316, 401, 402, 501, and 510 of the Clean Water Act, 33 U.S.C. 1251, 1311, 1314, 1316, 1318, 1326, 1341, 1342, 1361, and 1370. Publication of this proposed rule fulfills an obligation of the U.S. Environmental Protection Agency (EPA) under a consent decree in *Riverkeeper, Inc.* v. *Leavitt,* No. 93 Civ. 0314, (S.D.N.Y).

B. Purpose of Today's Proposed Regulation

Section 316(b) of the Clean Water Act provides that any standard established pursuant to section 301 or 306 of the Clean Water Act and applicable to a point source must require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. Today's proposed rule would establish requirements reflecting the best technology available for minimizing adverse environmental impact, applicable to the location, design, construction, and capacity of cooling water intake structures at Phase III facilities (Phase I and Phase II are described in section I. C of today's preamble). Today's notice proposes the following three possible options for defining which existing facilities would be subject to categorical national requirements based on the design intake flow of cooling water intake structures at a facility and waterbody type: (1) The facility has a total design intake flow of 50 million gallons per day (MGD) or more and withdraws from any waterbody; (2) the facility has a total design intake flow of 200 MGD or more and withdraws from any waterbody; or (3) the facility has a total design intake flow of 100 MGD or more and withdraws water specifically from an ocean, estuary, tidal river, or one of the Great Lakes. Today's notice also proposes a design intake flow threshold of greater than 2 MGD for new offshore oil and gas extraction facilities consistent with the design intake flow threshold for new facilities in the Phase I rule. Under each of these co-proposed regulatory options, a Phase III facility must use at least 25 percent of the water withdrawn exclusively for cooling purposes and meet other specified criteria in order to be within the scope of the rule (*see* Section II—Scope and Applicability of Proposed Rule).

C. Background

1. The Clean Water Act

The Federal Water Pollution Control Act, also known as the Clean Water Act (CWA), 33 U.S.C. 1251 *et seq.*, seeks to ''restore and maintain the chemical, physical, and biological integrity of the nation's waters.'' 33 U.S.C. 1251(a). The Clean Water Act establishes a comprehensive regulatory program, key elements of which are: (1) A prohibition on the discharge of pollutants from point sources to waters of the United States, except as authorized by the statute; (2) authority for EPA or authorized States or Tribes to issue National Pollutant Discharge Elimination System (NPDES) permits that regulate the discharge of pollutants; and, (3) requirements for limitations in NPDES permits based on effluent limitations guidelines and standards and water quality standards.

Section 316(b) addresses the adverse environmental impact caused by the intake of cooling water, not discharges into water. Despite this special focus, the requirements of section 316(b) are closely linked to several of the core elements of the NPDES permit program established under section 402 of the Clean Water Act to control discharges of pollutants into navigable waters. For example, while effluent limitations apply to the discharge of pollutants by NPDES-permitted point sources to waters of the United States, section 316(b) applies to facilities subject to NPDES requirements that withdraw water from waters of the United States for cooling and that use a cooling water intake structure to do so.

Section 402 of the Clean Water Act provides authority for EPA or an authorized State or Tribe to issue an NPDES permit to any person discharging any pollutant or combination of pollutants from a point source into waters of the United States. Forty-five States and one U.S. territory are currently authorized under section 402(b) to administer the NPDES permitting program. NPDES permits restrict the types and amounts of pollutants, including heat, that may be discharged from various industrial, commercial, and other sources of wastewater. These permits control the discharge of pollutants primarily by requiring dischargers to meet effluent limitations established pursuant to section 301 or section 306. Effluent

limitations may be based on Federal effluent limitations guidelines, new source performance standards, or the best professional judgment of the permit writer. Limitations based on these guidelines, standards, or best professional judgment are known as technology-based effluent limits. Where technology-based effluent limits are inadequate to ensure attainment of water quality standards applicable to the receiving water, section 301(b)(1)(C) of the Clean Water Act requires permits to include more stringent limits based on applicable water quality standards. NPDES permits also routinely include monitoring and reporting requirements, standard conditions, and special conditions. In addition, NPDES permits contain conditions to implement the requirements of section 316(b). Section 301 of the Clean Water Act prohibits the discharge of any pollutant by any person, except in compliance with specified statutory requirements, including section 402.

Section 510 of the Clean Water Act provides that, except as provided in the Clean Water Act, nothing in the Act shall preclude or deny the right of any State or political subdivision thereof to adopt or enforce any requirement respecting control or abatement of pollution; except that if a limitation, prohibition or standard of performance is in effect under the Clean Water Act, such State or political subdivision may not adopt or enforce any other limitation, prohibition or standard of performance which is less stringent than the limitation, prohibition or standard of performance under the Act. EPA interprets this to reserve for the States authority to implement requirements that are more stringent than the Federal requirements under State law. *PUD No. 1 of Jefferson County. Washington Dep't of Ecology*, 511 U.S. 700, 705 (1994).

Sections 301, 304, and 306 of the Clean Water Act require that EPA develop technology-based effluent limitations guidelines and new source performance standards that are used as the basis for technology-based minimum discharge requirements in wastewater discharge permits. EPA issues these effluent limitations guidelines and standards for categories of industrial dischargers based on the pollutants of concern discharged by the industry, the degree of control that can be attained using various levels of pollution control technology, consideration of economics, as appropriate to each level of control, and other factors identified in sections 304 and 306 of the Clean Water Act (such as non-water quality environmental impacts including energy impacts). EPA has promulgated regulations setting effluent limitations guidelines and standards under sections 301, 304, and 306 of the Clean Water Act for more than 50 industries. See 40 CFR 405 through 471. EPA has established effluent limitations guidelines and standards that apply to most of the industry categories that use cooling water intake structures (*e.g.*, steam electric power generation, iron and steel manufacturing, pulp and paper manufacturing, petroleum refining, and chemical manufacturing).

Section 316(b) states, in full:

> Any standard established pursuant to section 301 or section 306 of [the Clean Water] Act and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact.

The phrase ''best technology available'' in Clean Water Act section 316(b) is not defined in the statute, but its meaning can be understood in light of similar phrases used elsewhere in the Clean Water Act. See *Riverkeeper* v. *EPA*, slip op. at 11 (2nd Cir. Feb. 3, 2004) (noting that the cross-reference in Clean Water Act section 316(b) to Clean Water Act section 306 ''is an invitation to look at section 306 for guidance in determining what factors Congress intended the EPA to consider in determining 'best technology available' for new sources.'').

In sections 301 and 306, Congress directed EPA to set effluent discharge standards for new sources based on the ''best available demonstrated control technology'' and for existing sources based on the ''best available technology economically achievable.'' For new sources, section 306(b)(1)(B) directs EPA to establish ''standards of performance.'' The phrase ''standards of performance'' under section 306(a)(1) is defined as being the effluent reduction that is ''achievable through application of the best available demonstrated control technology, processes, operating methods or other alternatives. * * *'' This is commonly referred to as ''best available demonstrated technology'' or ''BADT.'' For existing dischargers, section 301(b)(1)(A) requires the establishment of effluent limitations based on ''the application of best practicable control technology currently available.'' This is commonly referred to as ''best practicable technology'' or ''BPT.'' Further, section 301(b)(2)(A) directs EPA to establish effluent limitations for certain classes of pollutants ''which shall require the application of the best available technology economically achievable.'' This is commonly referred to as ''best available technology'' or ''BAT.'' Section 301 specifies that both BPT and BAT limitations must reflect determinations made by EPA under Clean Water Act section 304. Under these provisions, the limitations on the discharge of pollutants from point sources are based upon the capabilities of the equipment or ''control technologies'' available to control those discharges.

The phrases ''best available demonstrated technology'' and ''best available technology''—like ''best technology available'' in Clean Water Act section 316(b)—are not defined in the statute. However, section 304 of the Clean Water Act specifies factors to be considered in establishing the best practicable control technology currently available and best available technology.

For best practicable control technology currently available, the Clean Water Act directs EPA to consider:

> the total cost of application of technology in relation to the effluent reduction benefits to be achieved from such application, and shall also take into account the age of the equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, non-water quality environmental impact (including energy requirements), and such other factors as [EPA] deems appropriate.

33 U.S.C. 1314(b)(1)(b).

For ''best available technology,'' the Clean Water Act directs EPA to consider:

> the age of equipment and facilities involved, the process employed, the engineering aspects * * * of various types of control techniques, process changes, the cost of achieving such effluent reduction, non-water quality environmental impacts (including energy requirements), and such other factors as [EPA] deems appropriate.

33 U.S.C. 1314(b)(2)(B).

Section 316(b) expressly refers to section 301, and the phrase ''best technology available'' is very similar to ''best available technology'' in that section. These facts, coupled with the brevity of section 316(b) itself, prompted EPA to look to section 301 and, ultimately, section 304 for guidance in determining the ''best technology available to minimize adverse environmental impact'' of cooling water intake structures for existing Phase II facilities.

By the same token, however, there are significant differences between section 316(b) and sections 301 and 304. *See Riverkeeper, Inc.* v. *United States Environmental Protection Agency*, slip op. at 13 (2nd Cir. Feb. 3, 2004) (''not every statutory directive contained [in

sections 301 and 306] is applicable'' to a section 316(b) rulemaking). Section 316(b) requires that cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. In contrast to the effluent limitations provisions, the object of the ''best technology available'' is explicitly articulated by reference to the receiving water: To minimize adverse environmental impact in the waters from which cooling water is withdrawn. This difference is reflected in EPA's past practices in implementing sections 301, 304, and 316(b). While EPA has established effluent limitations guidelines based on the efficacy of one or more technologies to reduce pollutants in wastewater, considering costs, but without necessarily considering the impact on the receiving waters, EPA has previously considered the costs of technologies in relation to the benefits of minimizing adverse environmental impact in establishing section 316(b) limits. *In Re Public Service Co. of New Hampshire,* 10 ERC 1257 (June 17, 1977); *In Re Public Service Co. of New Hampshire,* 1 EAD 455 (Aug. 4, 1978); *Seacoast Anti-Pollution League* v. *Costle,* 597 F. 2d 306 (1st Cir. 1979).

For this Phase III rulemaking, EPA therefore interprets Clean Water Act section 316(b) as authorizing EPA to consider not only technologies but also their effects on and benefits to the water from which the cooling water is withdrawn. Based on these two considerations, today's proposed rule establishes national requirements for facilities to install technology, as appropriate, that is technically available, economically practicable, cost-effective, and justified by the benefits to the source waterbody.

At this time, EPA is co-proposing all three options discussed above because it sees advantages to each. EPA is also considering an alternative under which EPA would not promulgate, at this time, categorical requirements under section 316(b) for cooling water intake structures unregulated by Phase I and Phase II. Rather, EPA would continue to rely on the best professional judgment of the permitting authority to determine the best technology available to minimize adverse environmental impact, in order to allow these requirements to be better tailored to local conditions.

2. Consent Decree

Publication of this proposal fulfills one of EPA's obligations to comply with a consent decree, as amended. The Second Amended Consent Decree, which is relevant to today's proposed rule, was filed on November 25, 2002, in the United States District Court, Southern District of New York, in *Riverkeeper, Inc.* v. *Leavitt,* No. 93 Civ 0314 (AGS). That case was brought against EPA by a coalition of individuals and environmental groups. The original Consent Decree, filed on October 10, 1995, provided that EPA was to propose regulations implementing section 316(b) by July 2, 1999, and take final action with respect to those regulations by August 13, 2001. Under subsequent interim orders, the Amended Consent Decree filed on November 22, 2000, and the Second Amended Consent Decree, EPA divided the rulemaking into three phases. EPA took final action on a rule governing cooling water intake structures used by new facilities (Phase I) on November 9, 2001 (66 FR 65255, December 18, 2001). EPA took final action on a rule governing cooling water intake structures used by large existing power producers (Phase II) on February 16, 2004 (69 FR 41576, July 9, 2004). The consent decree further requires that EPA propose regulations applicable to, at a minimum, existing facilities using cooling water intake structures with intake flows above a minimum threshold to be determined by EPA, in the following categories: power producers not covered by the Phase II regulations, pulp and paper manufacturing, petroleum and coal products manufacturing, chemical and allied products manufacturing, and primary metal manufacturing (Phase III). EPA is required to propose regulations for Phase III facilities by November 1, 2004, and take final action by June 1, 2006.

3. What Other EPA Rulemakings and Guidance Address Cooling Water Intake Structures?

In April 1976, EPA published a final rule under section 316(b) that addressed cooling water intake structures. 41 FR 17387 (April 26, 1976), see also the proposed rule at 38 FR 34410 (December 13, 1973). The rule added a new § 401.14 to 40 CFR Chapter I that reiterated the requirements of Clean Water Act section 316(b). It also added a new part 402, which included three sections: (1) Section 402.10 (Applicability), (2) § 402.11 (Specialized definitions), and (3) § 402.12 (Best technology available for cooling water intake structures). Section 402.10 stated that the provisions of part 402 applied to ''cooling water intake structures for point sources for which effluent limitations are established pursuant to section 301 or standards of performance are established pursuant to section 306 of the Act.'' Section 402.11 defined the terms ''cooling water intake structure,'' ''location,'' ''design,'' ''construction,'' ''capacity,'' and ''Development Document.'' Section 402.12 included the following language:

> The information contained in the Development Document shall be considered in determining whether the location, design, construction, and capacity of a cooling water intake structure of a point source subject to standards established under section 301 or 306 reflect the best technology available for minimizing adverse environmental impact.

In 1977, fifty-eight electric utility companies challenged those regulations, arguing that EPA had failed to comply with the requirements of the Administrative Procedure Act (APA) in promulgating the rule. Specifically, the utilities argued that EPA had neither published the Development Document in the **Federal Register** nor properly incorporated the document into the rule by reference. The United States Court of Appeals for the Fourth Circuit agreed and, without reaching the merits of the regulations themselves, remanded the rule. *Appalachian Power Co.* v. *Train,* 566 F.2d 451 (4th Cir. 1977). EPA later withdrew part 402. 44 FR 32956 (June 7, 1979). The regulation at 40 CFR 401.14, which reiterates the statutory requirement, remains in effect.

Since the Fourth Circuit remanded EPA's section 316(b) regulations in 1977, NPDES permit authorities have made decisions implementing section 316(b) on a case-by-case, site-specific basis. EPA published draft guidance addressing section 316(b) implementation in 1977. *See Draft Guidance for Evaluating the Adverse Impact of Cooling Water Intake Structures on the Aquatic Environment: Section 316(b) Pub. L. 92–500* (U.S. EPA, 1977). This draft guidance described the studies recommended for evaluating the impact of cooling water intake structures on the aquatic environment and recommended a basis for determining the best technology available for minimizing adverse environmental impact. The 1977 section 316(b) draft guidance states, ''The environmental-intake interactions in question are highly site-specific and the decision as to best technology available for intake design, location, construction, and capacity must be made on a case-by-case basis.'' (Section 316(b) Draft Guidance, U.S. EPA, 1977, p. 4). This case-by-case approach was also consistent with the approach described in the 1976 Development Document referenced in the remanded regulation.

The 1977 section 316(b) draft guidance suggested a general process for developing information needed to

support section 316(b) decisions and presenting that information to the permitting authority. The process involved the development of a site-specific study of the environmental effects associated with each facility that uses one or more cooling water intake structures, as well as consideration of that study by the permitting authority in determining whether the facility must make any changes for minimizing adverse environmental impact. Where adverse environmental impact is present, the 1977 draft guidance suggested a stepwise approach that considers screening systems, size, location, capacity, and other factors.

Although the draft guidance described the information that should be developed, key factors that should be considered, and a process for supporting section 316(b) determinations, it did not establish uniform technology-based national standards for best technology available for minimizing adverse environmental impact. Rather, the guidance left the decisions on the appropriate location, design, capacity, and construction of cooling water intake structures to the permitting authority. Under this framework, the Director determined whether appropriate studies have been performed, whether a given facility has minimized adverse environmental impact, and what, if any, technologies may be required.

4. Phase I New Facility Rule

On November 9, 2001, EPA took final action on regulations governing cooling water intake structures at new facilities. 66 FR 65255 (December 18, 2001). On December 26, 2002, EPA made minor changes to the Phase I regulations. 67 FR 78947. The final Phase I new facility rule (40 CFR 125, Subpart I) establishes requirements applicable to the location, design, construction, and capacity of cooling water intake structures at new facilities that withdraw greater than two (2) million gallons per day (MGD) and use at least twenty-five (25) percent of the water they withdraw solely for cooling purposes. In the new facility rule, EPA adopted a two-track approach. Under Track I, for facilities with a design intake flow more than 10 MGD, the intake flow of the cooling water intake structure is restricted, at a minimum, to a level commensurate with that which could be attained by use of a closed-cycle, recirculating cooling system. For facilities with a design intake flow greater than 2 MGD, the design through-screen intake velocity is restricted to 0.5 feet per second and the total quantity of intake is restricted to a proportion of the mean annual flow of a freshwater river or stream, or to maintain the natural thermal stratification or turnover patterns (where present) of a lake or reservoir except in cases where the disruption is beneficial, or to a percentage of the tidal excursions of a tidal river or estuary. If certain environmental conditions exist, an applicant with intake capacity greater than 10 MGD must select and implement appropriate design and construction technologies for minimizing impingement mortality and entrainment. (Applicants with 2 to 10 MGD flows are not required to reduce intake flow to a level commensurate with a closed-cycle, recirculating cooling system, but must install technologies for reducing entrainment at all locations.) Under Track II, the applicant has the opportunity to demonstrate to the Director that the technologies he employs will reduce the level of adverse environmental impact to a comparable level to what would be achieved by meeting the Track I requirements for restricting intake flow and velocity. As part of this demonstration, EPA initially had allowed the applicant to employ control measures other than reducing impingement mortality and entrainment, including restoration measures that would result in increases in fish and shellfish, comparable to the reduction in impingement mortality and entrainment it would achieve were it to implement the Track I intake flow and velocity requirements. However, in February 2004, the 2nd Circuit Court of Appeals issued a decision in response to several petitions challenging the final Phase I rule. The Court found that EPA exceeded its authority by allowing new facilities to comply with section 316(b) through restoration methods, and remanded that aspect of the rule to EPA. *Riverkeeper, Inc.* v. *EPA*, 358 F.3d 174, 191 (2nd Cir., 2004).

Directors may establish less stringent alternative requirements for a facility if compliance with the Phase I standards would result in compliance costs wholly out of proportion to those EPA considered in establishing the requirements at issue or would result in significant adverse impacts on local air quality, water resources, or local energy markets.

With the new facility rule, EPA promulgated national minimum requirements for the location, design, capacity, and construction of cooling water intake structures at new facilities. The final new facility rule establishes a reasonable framework that creates certainty for permitting of new facilities, while providing significant flexibility to take site-specific factors into account.

EPA specifically excluded new offshore oil and gas extraction facilities from the Phase I new facility rule, but committed to consider establishing requirements for such facilities in the Phase III rulemaking. 66 FR 65338 (December 18, 2001).

5. Phase II Existing Facility Rule

On February 16, 2004, EPA took final action on regulations governing cooling water intake structures at certain existing power producing facilities. 69 FR 41576 (July 9, 2004). The final Phase II rule applies to existing facilities that are point sources; that, as their primary activity, both generate and transmit electric power or generate electric power for sale or transmission; that use or propose to use a cooling water intake structure with a total design intake flow of 50 MGD or more to withdraw water from waters of the United States; and that use at least 25 percent of the withdrawn water exclusively for cooling purposes.

Under the Phase II rule, EPA established performance standards for the reduction of impingement mortality and, when appropriate, entrainment (*see* 40 CFR 125.94). The performance standards consist of ranges of reductions in impingement mortality and/or entrainment (*e.g.*, reduce impingement mortality by 80 to 95 percent and/or entrainment by 60 to 90 percent). These performance standards reflect the best technology available for minimizing adverse environmental impacts. The type of performance standard applicable to a particular facility (*i.e.*, reductions in impingement mortality only or impingement mortality and entrainment) is based on several factors, including the facility's location (*i.e.*, source waterbody), rate of use (capacity utilization rate), and the proportion of the waterbody withdrawn. In most cases, EPA believes that these performance standards can be met using design and construction technologies or operational measures. The performance standards also can be met, in whole or in part, by using restoration measures, following consideration of design and construction technologies or operational measures, and provided such measures meet certain specified requirements. (*See* 40 CFR 125.94(c)).

The Phase II rule identifies five alternatives to achieve compliance with the requirements for best technology available for minimizing adverse environmental impacts associated with cooling water intake structures. A facility must demonstrate to the Director one of the following: (1) That it has already reduced its flow commensurate with a closed-cycle recirculating system

(to meet performance standards for impingement and entrainment), or that it has already reduced its design intake velocity to 0.5 feet per second or less (to meet the impingement performance standard only); (2) that its current cooling water intake structure configuration meets the applicable performance standards; (3) that it has selected design and construction technologies, operational measures, and/or restoration measures that, in combination with any existing design and construction technologies, operational measures, and/or restoration measures, meet the applicable performance standards; (4) that it meets the applicability criteria and has installed and is properly operating and maintaining a rule-specified and/or State-specified approved design and construction technology (*i.e.*, submerged cylindrical wedgewire screen) in accordance with 40 CFR 125.99(a) or an alternative technology that meets the appropriate performance standards and is approved by the Director in accordance with 40 CFR 125.99(b); or (5) that its costs of compliance would be significantly greater than the costs considered by the Administrator for a like facility to meet the applicable performance standards, or than the benefits of meeting the applicable performance standards at the facility. A discussion of the legal authority and basis for the use of the cost test is found in section VI of this preamble.

During the first permit term and subsequent permit terms, a facility that chooses compliance alternatives two (2) through five (5), as described above, may request that compliance with the requirements of the rule be determined based on the implementation of a Technology Installation and Operation Plan (TIOP), indicating how the facility will install and ensure the efficacy, to the extent practicable, of design and construction technologies and/or operational measures, and/or a Restoration Plan. Adaptive management practices must be employed to ensure compliance during subsequent permit terms. The TIOP must be developed and submitted to the Director in accordance with 40 CFR 125.95(b)(4)(ii). The Restoration Plan must be developed in accordance with 40 CFR 125.95(b)(5).

6. Public Participation

EPA worked extensively with stakeholders from the industry, public interest groups, State agencies, and other Federal agencies in the development of this proposed rule. EPA included industry groups, environmental groups, and other government entities in the development, testing, refinement, and completion of the section 316(b) survey, which was used as a primary source of data for the Phase III proposed rule. As discussed in section III of today's preamble, the survey, ''Information Collection Request, Detailed Industry Questionnaires: Phase II Cooling Water Intake Structures & Watershed Case Study Short Questionnaire,'' was initiated in 1997, and was used to collect data during 1998. EPA conducted two public meetings on section 316(b) issues. In June of 1998, EPA conducted a public meeting focused on a draft regulatory framework for assessing potential adverse environmental impact from impingement mortality and entrainment. 63 FR 27958 (May 21, 1998). A second public meeting was held in September of 1998, and focused on technology, cost, and mitigation issues. 63 FR 40683 (July 30, 1998). In addition, in September of 1998, and April of 1999, EPA participated in technical workshops sponsored by the Electric Power Research Institute on issues relating to the definition and assessment of adverse environmental impact. EPA also participated in other industry conferences, and has met with representatives of industry and environmental groups.

In the months leading up to publication of the proposed Phase I rule, EPA conducted a series of stakeholder meetings to review the draft regulatory framework for the proposed rule and invited stakeholders to provide their recommendations. Participants included representatives of the electric power industry, as well as the petroleum refining, pulp and paper, and iron and steel industries. EPA also met with environmental groups, States, and interstate groups. After publication of the proposed Phase I rule, EPA continued to meet with stakeholders. Summaries of these meetings are in the docket. EPA also received many comments on the Phase I proposed rule (65 FR 49059, August 10, 2000) and Notice of Data Availability (NODA). (66 FR 28853, May 25, 2001). These comments informed the development of the Phase II rule and this Phase III proposed rule.

In January 2001, EPA attended technical workshops organized by the Electric Power Research Institute and the Utilities Water Act Group. These workshops focused on key issues associated with different regulatory approaches considered under the Phase I proposed rule and alternatives for addressing section 316(b) requirements.

On May 23, 2001, EPA held a day-long forum to discuss specific issues associated with the development of regulations under section 316(b) of the Clean Water Act. 66 FR 20658 (April 24, 2001). At the meeting, 17 experts from industry, public interest groups, States, and academia reviewed and discussed the Agency's preliminary data on cooling water intake structure technologies that are in place at existing facilities and the costs associated with the use of available technologies for reducing impingement mortality and entrainment. Over 120 people attended the meeting.

On August 21, 2001, EPA participated in a technical symposium sponsored by the Electric Power Research Institute in association with the American Fisheries Society on issues relating to the definition and assessment of adverse environmental impact under section 316(b) of the Clean Water Act.

During development of the Phase I and Phase II rules, EPA coordinated with the Nuclear Regulatory Commission (NRC) to ensure that there would not be a conflict with NRC safety requirements. NRC reviewed the proposed Phase II rule and did not identify any apparent conflict with nuclear plant safety. NRC licensees would continue to be obligated to meet NRC requirements for design and reliable operation of cooling systems. NRC recommended that EPA consider adding language which states that in cases of conflict between an EPA requirement and an NRC safety requirement, the NRC safety requirement takes precedence. EPA added language to address this concern in the Phase II final rule and this proposed rule.

EPA sponsored a *Symposium on Cooling Water Intake Technologies to Protect Aquatic Organisms,* on May 6–7, 2003. This symposium brought together professionals from Federal, State, and Tribal regulatory agencies; industry; environmental organizations; engineering consulting firms; science and research organizations; academia; and others concerned with mitigating harm to the aquatic environment by cooling water intake structures. Efficacy and costs of various technologies to mitigate impacts to aquatic organisms from cooling water intake structures, as well as research and other future needs, were discussed.

During the development of this proposed regulation, EPA met several times with trade associations whose members would be subject to the Phase III requirements. EPA also conducted Phase III-specific data collection activities, including a study of entrainment at manufacturing facilities, contacting Phase III facilities to request

biological studies and conducted an industry survey of offshore oil and gas extraction facilities and seafood processing vessels.

Finally, EPA convened a Small Business Advocacy Review (SBAR) panel (in accordance with the Regulatory Flexibility Act section 609(b) as amended by the Small Business Regulatory and Enforcement Fairness Act) to provide information to small entities and receive feedback during the Phase III rulemaking process. EPA hosted a pre-panel outreach meeting for small entities potentially subject to Phase III on January 22, 2004. The SBAR panel held an outreach meeting with small entity representatives (SERs) on March 16, 2004. Based on the information gathered from the participating small entities during these outreach meetings and subsequent correspondence, the SBAR panel produced a final report to the EPA Administrator on April 27, 2004. Results of the final report were considered in the development of this proposed Phase III rule.

These coordination efforts and all of the meetings described in this section, as well as the comments submitted on the Phase I and II section 316(b) rules and EPA's response to these comments, are documented or summarized in the dockets for these three rules. The Administrative Record for today's proposal includes all materials from the Phase I, Phase II, and Phase III section 316(b) rule dockets.

II. Scope and Applicability of the Proposed Rule

Based on the co-proposed flow thresholds based options in today's proposed rule, the proposed national categorical requirements would apply to two groups of facilities: (1) Existing manufacturing facilities (including but not limited to chemical, metal, pulp and paper, and petroleum refining facilities), and (2) new offshore oil and gas extraction facilities. In today's proposed rule, the term ''new offshore oil and gas extraction facility'' is defined to include facilities in both the offshore and the coastal subcategories of EPA's Oil and Gas Extraction Point Source Category for which effluent limitations are established at 40 CFR part 435. Although the term ''offshore'' denotes only one of these two subcategories for purposes of the effluent guidelines, EPA decided that it was more efficient to use the term ''offshore'' to denote facilities in either subcategory for purposes of today's rule because the proposed requirements are the same for both offshore and coastal facilities and the term ''offshore'' is commonly understood to include any facilities not located on land. EPA requests comment on whether this definition is likely to cause confusion over the scope of covered facilities. In order to be covered by today's proposed rule, these facilities would need to use cooling water intake structures to withdraw water from waters of the U.S. and meet all other applicability criteria, described below.

Existing facilities that meet all of the following criteria would be subject to today's proposed rule, if promulgated as proposed (*see* § 125.101).

- The facility is a point source that has or is required to have an NPDES permit under section 402 of the Clean Water Act;
- The facility is an existing facility not subject to the Phase II regulation;
- The facility uses at least 25 percent of water withdrawn exclusively for cooling purposes, measured on an average annual basis; and
- The facility uses, or proposes to use, cooling water intake structures, including a cooling water intake structure operated by an independent supplier (other than a public water system), with a total design intake flow equal to or greater than a certain threshold to withdraw cooling water from waters of the United States.

Today's proposed rule co-proposes three options based on design intake flow and source waterbody type for defining which existing facilities are Phase III existing facilities subject to categorical national requirements:

- The facility has a total design intake flow of 50 MGD or more, and withdraws from any waterbody type (''50 MGD All Waterbodies'');
- The facility has a total design intake flow of 200 MGD or more, and withdraws from any waterbody type (''200 MGD All Waterbodies'');
- The facility has a total design intake flow of 100 MGD or more and withdraws water from an ocean, estuary, tidal river, or one of the Great Lakes (''100 MGD Certain Waterbodies'').

A facility meeting the above criteria, including any flow threshold EPA adopts after considering comments on the three co-proposed options, would be referred to as a ''Phase III existing facility.'' If an existing facility does not meet the relevant Phase II or Phase III cooling water use and intake flow thresholds by itself, and is co-located with an existing facility that is not subject to the Phase II regulation (*e.g.*, a power producing facility below the Phase II flow threshold, or a manufacturing facility), both facilities would still be subject to Phase III requirements if the cooling water used collectively by the co-located facilities meets the applicable thresholds (and the facilities meet the other requisite Phase III criteria). Co-located facilities adjoin each other and are under common ownership, operation, or management. If a facility is a point source that uses a cooling water intake structure and has, or is required to have, an NPDES permit, but does not meet the proposed applicable design intake flow/source waterbody threshold or the 25 percent cooling water use threshold, it would continue to be subject to permit conditions implementing CWA section 316(b) set by the permit director on a case-by-case, best professional judgment basis.

Today's notice also proposes requirements for new offshore oil and gas extraction facilities, which were specifically excluded from the Phase I new facility rule. (40 CFR 125 Subpart I). Section II.B of the preamble discusses what constitutes a ''new'' offshore oil and gas extraction facility for purposes of the section 316(b) proposed Phase III rule. Requirements for new offshore oil and gas extraction facilities are proposed in 40 CFR Subpart N. EPA is seeking comment on the requirements contained in this subpart. EPA is not seeking comment on the Phase I rule that EPA promulgated in 2001.

Finally, under today's proposed rule a seafood processing vessel or an offshore liquefied natural gas import terminal would not be subject to national categorical requirements. Such a facility could be subject to permit conditions implementing CWA section 316(b) set by the permit director on a case-by-case, best professional judgment basis where the facility is a point source that uses a cooling water intake structure and has, or is required to have, an NPDES permit.

A. What Is a ''New'' Offshore Oil and Gas Extraction Facility for Purposes of the Section 316(b) Proposed Phase III Rule?

For purposes of this proposed rule, new offshore oil and gas extraction facilities are those facilities that are subject to the Oil and Gas Extraction Point Source Category Effluent Guidelines (*i.e.*, 40 CFR 435.10 Offshore Subcategory or 40 CFR 435.40 Coastal Subcategory); that commence construction more than 60 days after publication of the final rule; and that meet all other aspects of the ''new facility'' definition in § 125.83 (other than the date for commencing construction). In other words, in order to be covered by today's proposed rule, a new offshore oil and gas extraction facility would have to be a new source or new discharger per 40 CFR 122.2 and 122.29, a greenfield or stand-alone

facility, and use either a newly constructed cooling water intake structure, or an existing cooling water intake structure whose design capacity is increased to accommodate the intake of additional cooling water.

B. What Is an ''Existing Facility'' for Purposes of the Section 316(b) Proposed Phase III Rule?

In today's proposed rule, the definition of ''existing facility'' is the same as in the Phase II rule except for additional language addressing new offshore oil and gas extraction facilities: any facility that commenced construction on or before January 17, 2002 (or 60 days after publication of the final rule for an offshore oil and gas extraction facility), as described in 40 CFR 122.29(b)(4).[1] January 17, 2002 is the effective date of the Phase I new facility rule and, therefore, the date for distinguishing new facilities from existing ones. However, offshore oil and gas extraction facilities were not subject to the Phase I new facility rule, but rather, would be subject to requirements under this proposed Phase III rule. Therefore, the effective date of the final Phase III rule would be the date for distinguishing new offshore oil and gas extraction facilities from existing ones. An ''existing facility'' under this proposed rule would include modifications and additions to existing facilities, that do not meet the definition of a new facility under the Phase I rule (40 CFR 125.83). That definition states:

New facility means any building, structure, facility, or installation that meets the definition of a ''new source'' or ''new discharger'' in [other NPDES regulations] and is a greenfield or stand-alone facility; commences construction after January 17, 2002; and uses either a newly constructed cooling water intake structure, or an existing cooling water intake structure whose design capacity is increased to accommodate the intake of additional cooling water. New facilities include only ''greenfield'' and ''stand-alone'' facilities. A greenfield facility is a facility that is constructed at a site at which no other source is located or that totally replaces the process or production equipment at an existing facility (*see* 40 CFR 122.29(b)(1)(i) and (ii)). A stand-alone facility is a new, separate facility that is constructed on property where an existing facility is located and whose processes are substantially independent of the existing facility at the same site (*see* 40 CFR 122.29(b)(1)(iii). New facility does not include new units that are added to a facility for purposes of the same general industrial operation (for example, a new peaking unit at an electrical generating station).[2]

The definition in today's proposed regulation is intended to be consistent with EPA's definition of new facility in the Phase I rule (§ 125.83) and to ensure that sources excluded from the definition of new facility in the Phase I rule are captured by the definition of existing facility.

The determination of whether a facility is ''new'' or ''existing'' is focused on the point source discharger—not on the cooling water intake structure. In other words, modifications or additions to the cooling water intake structure (or even the total replacement of an existing cooling water intake structure with a new one) does not convert an otherwise unchanged existing facility into a new facility, regardless of the purpose of such changes. Rather, the determination as to whether a facility is new or existing focuses on the point source itself, *i.e.*, whether it is a greenfield facility or a stand-alone facility.

Under this proposed rule, an existing manufacturing facility that replaces or modifies an existing generating or manufacturing unit would remain subject to regulation as a Phase III existing facility, unless (1) the existing facility were completely demolished and another facility constructed in its place (a ''greenfield'' facility), or a separate facility with substantially independent processes were constructed on the property (a ''stand-alone'' facility) and (2) the new facility used either a new intake structure or the existing structure with an increased design capacity. To illustrate, an existing facility that undertook the following facility modifications or additions would continue to be characterized as an existing facility—not a new facility—under today's proposed rule:

- An existing manufacturing facility undergoes a modification of its process short of total replacement of the process and concurrently increases the design capacity of its existing cooling water intake structures;
- An existing manufacturing facility builds a new process at its site for purposes of the same industrial operation and concurrently increases the design capacity of its existing cooling water intake structures;
- An existing manufacturing facility completely rebuilds its process but uses the existing cooling water intake structure with no increase in design capacity.

Phase III existing facilities subject to today's proposed rule would also include point sources that are new users of cooling water intake structures, but do not meet the definition of new facility under § 125.83. For example, an existing facility may have historically withdrawn its cooling water from a municipal or other source, but then begins to withdraw cooling water from a water of the United States. This facility would be considered an existing facility because it is not a ''greenfield'' or ''stand alone'' facility within the meaning of the new facility rule. Similarly, a facility that previously relied on unit processes that do not require cooling water, and then adds or modifies a unit process for purposes of the same industrial operation such that cooling water is subsequently required, would also be regulated as an existing facility, not a new facility, under 316(b).

C. What Is ''Cooling Water'' and What Is a ''Cooling Water Intake Structure?'

Today's proposed rule would adopt for Phase III facilities the same definition of a ''cooling water intake structure'' that applies to new facilities under the final Phase I rule and existing facilities under the final Phase II rule. A cooling water intake structure would be defined as the total physical structure and any associated constructed waterways used to withdraw cooling

[1] Construction is commenced if the owner or operator has undertaken certain installation and site preparation activities that are part of a continuous on-site construction program, and it includes entering into certain specified binding contractual obligations as one criterion (40 CFR 122.29(b)(4)).

[2] The Phase I rule also listed examples of facilities that would be ''new'' facilities and facilities that would ''not be considered a 'new facility' '' in two numbered paragraphs. These read as follows:

''(1) Examples of 'new facilities' include, but are not limited to: the following scenarios:

''(i) A new facility is constructed on a site that has never been used for industrial or commercial activity. It has a new cooling water intake structure for its own use.

''(ii) A facility is demolished and another facility is constructed in its place. The newly-constructed facility uses the original facility's cooling water intake structure, but modifies it to increase the design capacity to accommodate the intake of additional cooling water.

''(iii) A facility is constructed on the same property as an existing facility, but is a separate and independent industrial operation. The cooling water intake structure used by the original facility is modified by constructing a new intake bay for the use of the newly constructed facility or is otherwise modified to increase the intake capacity for the new facility.

''(2) Examples of facilities that would not be considered a 'new facility' include, but are not limited to, the following scenarios:

''(i) A facility in commercial or industrial operation is modified and either continues to use its original cooling water intake structure or uses a new or modified cooling water intake structure.

''(ii) A facility has an existing intake structure. Another facility (a separate and independent industrial operation), is constructed on the same property and connects to the facility's cooling water intake structure behind the intake pumps, and the design capacity of the cooling water intake structure has not been increased. This facility would not be considered a 'new facility' even if routine maintenance or repairs that do not increase the design capacity were performed on the intake structure.''

water from waters of the Unites States. Under this definition, the cooling water intake structure extends from the point at which water is withdrawn from the surface water source up to and including the intake pumps. Today's proposed rule also would adopt the definition of ''cooling water'' used in the Phase I and Phase II rules: water used for contact or noncontact cooling, including water used for equipment cooling, evaporative cooling tower makeup, and dilution of effluent heat content. The definition specifies that the intended use of cooling water is to absorb waste heat rejected from the processes used or auxiliary operations on the facility's premises. The definition also indicates that water used in a manufacturing process either before or after it is used for cooling is process water and would not be considered cooling water for purposes of determining whether the facility was using 25 percent or more of the water withdrawn for cooling purposes. This clarification is necessary because cooling water intake structures typically bring water into a facility for numerous purposes, including use in industrial processes; use as circulating water, service water, or evaporative cooling tower makeup water; dilution of effluent heat content; equipment cooling; and air conditioning. This is particularly true for manufacturers addressed under this proposed rule, who often seek to reduce water use and increase efficiency through water reuse. EPA does not wish to create a disincentive to such improved efficiency and recognizes that to do so could result in other forms of environmental impacts. Consequently, and consistent with the Phase I and Phase II rules, only the water used exclusively for cooling purposes would be counted when determining whether the 25 percent threshold in § 125.101(a)(4) or § 125.131(a)(2) is met.

This proposed definition of ''cooling water intake structure'' differs from the definition provided in the 1977 *Draft Guidance for Evaluating the Adverse Impact of Cooling Water Intake Structures on the Aquatic Environment: Section 316(b) Pub. L. 92–500* (U.S. EPA, 1977). The proposed rule definition would clarify that the cooling water intake structure includes the physical structure that extends from the point at which water is withdrawn from the surface water up to and including the intake pumps. Inclusion of the term ''associated constructed waterways'' in today's proposed rule is intended to clarify that the definition includes those canals, channels, connecting waterways, and similar structures that may be built or modified to facilitate the withdrawal of cooling water. The explicit inclusion of the intake pumps in the definition reflects the key role pumps play in determining the capacity (*i.e.,* dynamic capacity) of the intake. These pumps, which bring in water, are an essential component of the cooling water intake structure since without them the intake structure could not work as designed.

D. Would My Facility Be Covered if It Withdraws From Waters of the United States?

The requirements proposed today would apply to cooling water intake structures that have the design capacity to withdraw amounts of water equal to or greater than the specified proposed intake flow thresholds from ''waters of the United States.'' Waters of the United States include the broad range of surface waters that meet the regulatory definition at 40 CFR 122.2, which includes lakes, ponds, reservoirs, nontidal rivers or streams, tidal rivers, estuaries, fjords, oceans, bays, and coves. These potential sources of cooling water may be adversely affected by impingement mortality and entrainment.

Some facilities discharge heated water to cooling ponds, then withdraw water from the ponds for cooling purposes. EPA recognizes that cooling ponds may, in certain circumstances, constitute part of a closed-cycled cooling system. See, *e.g.,* § 125.102. However, EPA does not intend that this proposed rule would change the regulatory status of cooling ponds. Cooling ponds are neither categorically included nor categorically excluded from the definition of ''waters of the United States'' at 40 CFR 122.2. EPA interprets 40 CFR 122.2 to give permit writers discretion to regulate cooling ponds as ''waters of the United States'' where cooling ponds meet the definition of ''waters of the United States.'' The determination of whether a particular cooling pond is a water of the United States is to be made by the permit writer on a case-by-case basis, informed by the discussions in *Solid Waste Agency of Northern Cook County (SWANCC)* v. *U.S. Army Corps of Engineers,* 531 U.S. 159 (2001), and subsequent case law. Therefore, facilities that withdraw cooling water from cooling ponds that are waters of the United States and that would meet today's other proposed criteria for coverage (including the requirement that the facility has or will be required to obtain an NPDES permit) would be subject to today's proposed rule. The EPA and the U.S. Army Corps of Engineers have jointly issued jurisdictional guidance concerning the term ''waters of the United States'' in light of the Supreme Court's decision in *Solid Waste Agency of Northern Cook County* v. *U.S. Army Corps of Engineers,* 531 U.S. 159 (2001) (SWANCC). A copy of that guidance was published as an Appendix to an Advanced Notice of Proposed Rulemaking on the definition of the phrase ''waters of the U.S.,'' see 68 FR 1991 (January 15, 2003), and may be obtained at *http://www.epa.gov/owow/wetlands/ANPRM–FR.pdf.* Proposed § 125.101(d) also provides, similar to the Phase I and Phase II rules, that facilities that obtain cooling water from a public water system or use treated effluent are not deemed to be using a cooling water intake structure for purposes of this proposed rule.

E. Would My Facility Be Covered if It Is a Point Source Discharger?

Today's proposed rule would apply only to facilities that are point sources (*i.e.,* have an NPDES permit or are required to obtain one) because they discharge or might discharge pollutants, including storm water, from a point source to waters of the United States. This is the same requirement EPA included in the Phase I and Phase II final rules (*see,* 40 CFR 125.81(a)(1), and 40 CFR 125.91(a)(1), respectively). Requirements for complying with section 316(b) will continue to be applied through NPDES permits.

Based on the Agency's review of potential Phase III facilities that employ cooling water intake structures, the Agency anticipates that most Phase III facilities that would be subject to this proposed rule control the intake structure that supplies them with cooling water, and discharge some combination of their cooling water, wastewater, and storm water to a water of the United States through a point source regulated by an NPDES permit. In this scenario, the requirements for the cooling water intake structure would be specified in the facility's NPDES permit. In the event that a Phase III facility's only NPDES permit is a general permit (*e.g.,* for oil and gas production) or a general permit for storm water discharges, the Agency anticipates that the Director may want to write an individual NPDES permit containing requirements for the facility's cooling water intake structure. Alternatively, requirements applicable to cooling water intake structures could be incorporated into general permits. If requirements are placed into a general permit, they must meet the criteria set out at 40 CFR 122.28.

The Agency also recognizes that some facilities that have or are required to have an NPDES permit might not own

and operate the intake structure that supplies their facility with cooling water. For example, manufacturing facilities operated by separate entities might be located on the same, adjacent, or nearby property(ies); one of these facilities might take in cooling water and then transfer it to other facilities prior to discharge of the cooling water to a water of the United States. Proposed § 125.101(c) of today's proposed rule would address such a situation. It provides that use of a cooling water intake structure includes obtaining cooling water by any sort of contract or arrangement with one or more independent suppliers of cooling water if the supplier withdraws water from waters of the United States but is not itself subject to regulations under 316(b). This provision is intended to prevent facilities from circumventing the requirements of today's proposed rule by creating arrangements to receive cooling water from an entity that is not itself subject to national categorical requirements (*e.g.,* a facility that is not a point source).

For facilities that have or are required to have NPDES permits that do not directly control the intake structures that supply their facilities with cooling water, proposed § 125.101(d) also provides, similar to the Phase I and II rules, that facilities that obtain cooling water from a public water system or use treated effluent are not deemed to be using a cooling water intake structure for purposes of this proposed rule.

As stated in the preamble to the final Phase I rule (66 FR 65256, December 18, 2001), the Agency would encourage the Director to closely examine scenarios in which a facility withdraws significant amounts of cooling water from waters of the United States but is not required to obtain an NPDES permit. As appropriate, under this proposed rule, the Director would apply other legal requirements, such as section 404 or 401 of the Clean Water Act, the Coastal Zone Management Act, the National Environmental Policy Act, the Endangered Species Act, or similar State or Tribal authorities to address adverse environmental impact caused by cooling water intake structures at those facilities.

F. What Are the Cooling Water Use and Design Intake Flow Thresholds in This Proposed Rule?

This proposed rule would apply to existing facilities that meet the following thresholds: (1) Use at least twenty-five (25) percent of the water withdrawn exclusively for cooling purposes (measured on an average annual basis), and (2) have a total design intake flow equal to or greater than one of the three proposed thresholds , but are not subject to the Phase II rule. As previously discussed, EPA is proposing three possible flow threshold-based options in today's proposed rule (*i.e.,* 50 MGD, 200 MGD, and 100 MGD [3]). The facility would also have to meet the other applicability criteria defined in § 125.101.

The 25 percent exclusive cooling use threshold is the same as employed in the Phase I and II regulations. As in the Phase I and Phase II rules, water used for both cooling and non-cooling purposes would not count towards the 25 percent threshold. Thus, the proposed rule would not discourage the reuse of cooling water as process water or vice versa. Water that serves as cooling water but is either previously or subsequently used as process water would not be considered cooling water for purposes of determining whether the 25 percent threshold is met. Water withdrawn for non-cooling purposes would include water withdrawn for warming by liquified natural gas facilities, water used to power hydro-electric plants, and water withdrawn for public water systems by desalinization facilities.

Today's notice proposes three different options for defining which existing facilities are Phase III existing facilities subject to categorical national requirements. These options include existing facilities having a total design intake flow of: 50 MGD or more; 200 MGD or more; or 100 MGD or more if the facility withdraws water from an ocean, tidal river, estuary, or Great Lake. EPA is co-proposing these options because EPA believes that all three reflect potentially viable alternatives for balancing the many factors EPA considers in establishing best technology available for minimizing adverse environmental impact. These factors include the percentage of cooling water flow subject to national requirements, costs, benefits, cost-effectiveness, permitting burden and the need for flexibility in implementation, projected closures, and potential impacts on small businesses. Each of these factors are permissible for consideration under the CWA and each of these co-proposed options will fulfill CWA requirements. For example, considerations of costs, benefits, economically practicability and cost-effectiveness are appropriate factors under CWA sections 301 and 304 (*e.g.,* see discussion of Agency authority in section I). In addition, EPA is required to consider small business impacts under the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act. Accordingly, the discussion below focuses on the relative advantages and disadvantages of these co-proposed options and the proposed regulatory language reflects all three options.

i. Total Design Intake Flow of 50 MGD or More

Under this co-proposed option, facilities with a design intake flow of 50 MGD or greater, and that meet the other criteria in § 125.101, would be subject to the performance standards and compliance alternatives proposed in today's rule discussed below. Under this option, section 316(b) permit conditions for existing facilities with a design intake flow of less than 50 MGD would continue to be established on a case-by-case, best professional judgment basis.

EPA is co-proposing the 50 MGD threshold based on several factors. With a 50 MGD flow threshold, the proposed rule would regulate 75 percent of the design intake capacity, and 23 percent of the facilities (155 facilities) potentially covered by the Phase III rule,[4] thus subjecting the majority of design intake flows potentially included within the scope of the Phase III existing facility rule to national performance requirements. Use of a 50 MGD threshold would focus national section 316(b) requirements on those Phase III existing facilities with moderate to large design intake flows. These facilities pose a greater potential for causing significant adverse environmental impacts than those withdrawing less than 50 MGD. Assuming full implementation of the Phase II rule and today's proposed rule, at the co-proposed 50 MGD threshold, section 316(b) program requirements would regulate more than 97 percent of the total cooling water withdrawals associated with existing facilities. In addition, EPA estimates that use of a 50 MGD threshold would avoid facility closures under this proposed rule, and would reduce the cost of the proposed rule to permittees compared with the costs of a lower threshold.

[3] **Note:** the 100 MGD flow threshold also specifies withdrawal from certain source waterbody types. The other proposed flow thresholds are not linked to source waterbody types.

[4] Facilities ''potentially covered by the Phase III rule'' include all existing manufacturing and power producing facilities greater than 2 MGD that were not covered by the Phase II rule. There are an estimated 683 manufacturing and electric generating facilities (survey weighted) potentially covered by the Phase III rule, with a total design intake flow of 40,441 MGD.

EPA estimates this option would cost $47.3 to $50.1 million [5] or $348,000 to $368,000 on average annually per facility. Quantified benefits are $1.5 million to $1.9 million (annualized use value). Because this option covers the most facilities, it may also have the greatest ecological protection benefits, which EPA was not able to quantify. EPA estimates that this option would provide the highest quantified and monetized benefits of the co-proposed options but would also have the highest annualized costs, resulting in the lowest quantified benefits-to-cost ratio and the lowest (greatest negative) quantified net benefits among these options. See section X of this preamble for further discussion of benefits and costs.

Finally, the co-proposed 50 MGD threshold would exclude small businesses from national rule requirements. This is consistent with the recommendations of the Small Business Advocacy Review Panel final report that EPA analyze a range of potential thresholds, particularly those between 20 MGD and 50 MGD, as a means of reducing potential economic impacts on small businesses while still achieving desired environmental benefits under the rule. See section XI.C for additional information. EPA estimates that setting an applicability threshold at 50 MGD would exclude all existing small entities potentially subject to the Phase III rule.

ii. Total Design Intake Flow of 200 MGD or More

Under this co-proposed option, facilities with a design intake flow of 200 MGD or greater and that meet the other criteria in § 125.101, would be subject to the performance standards and compliance alternatives proposed in today's notice and discussed above. Under this option, section 316(b) permit conditions for existing facilities not covered under the Phase II rule, with a design intake flow of less than 200 MGD, would continue to be established on a case-by-case, best professional judgment basis.

EPA is co-proposing the 200 MGD threshold based on several factors. With a 200 MGD flow threshold, the proposed rule would regulate 45 percent of the design intake capacity and approximately 5% of the facilities potentially covered by the Phase III rule. Assuming full implementation of the Phase II rule and today's proposed rule, at the co-proposed 200 MGD threshold, section 316(b) program requirements would regulate more than 94 percent of the total cooling water withdrawals associated with existing facilities withdrawing greater than 2 MGD.

EPA estimates this option would cost $22.8 to $24.1 million or $912,000 to $964,000 on average annually per facility. Quantified benefits are $0.98 to $1.26 million (annualized use value). The option would have a higher benefit-to-cost ratio yielding 66 percent of the quantified benefits at 48% of the costs and greater (lower negative) quantified net benefits compared to the 50 MGD option.

EPA estimates that use of a 200 MGD threshold would avoid facility closures under this proposed rule and would exclude all existing small entities.

iii. Facility Has a Total Design Intake Flow of 100 MGD or More and Withdraws Water From an Ocean, Tidal River, Estuary, or Great Lake

Under this co-proposed option, facilities located on estuaries, oceans, tidal rivers or streams, or one of the Great Lakes, with a design intake flow of 100 MGD or greater, and that meet the other criteria in § 125.101, would be subject to the performance standards and compliance alternatives proposed in today's rule and discussed below. Under this regulatory option, section 316(b) permit conditions for all existing facilities not covered under the Phase II rule, and located on freshwater rivers and streams or lakes and reservoirs, or with a design intake flow of less than 100 MGD would continue to be established on a case-by-case, best professional judgment basis.

Under this co-proposed option, 4 percent of the facilities potentially subject to regulation under Phase III would be subject to national requirements, and 18 percent of total design intake capacity associated with potential Phase III facilities would be addressed by such national requirements. Assuming full implementation of the Phase II rule and today's proposed rule, at the co-proposed 100 MGD threshold, section 316(b) program requirements would regulate more than 91 percent of the total cooling water withdrawals associated with existing facilities.

EPA estimates this option would cost $17.6 to $18.2 million or $926,000 to $958,000 on average annually per facility. Quantified benefits are $1.1 to 1.4 million (annualized use value). EPA estimates that this option would provide the second highest quantified benefits of the co-proposed options, and would have the lowest annualized costs when compared with the other two options, resulting in the highest quantified benefits-to-costs ratio and highest (least negative) quantified net benefits among the three options. This option would provide about 75 percent of the quantified benefits of the 50 MGD flow threshold option at about 36 percent of the cost by focusing the rule requirements on the most sensitive waterbodies.

EPA estimates that use of a 100 MGD threshold would avoid facility closures under this proposed rule and would exclude all existing small entities.

EPA requests comment on all aspects of each of these co-proposed options, including whether lower (*e.g.,* 20 MGD) or higher (*e.g.,* 250 MGD) thresholds should be considered, as well as whether different conditions (*e.g.,* related to waterbody type) should be combined with these or other thresholds. EPA also solicits comment on the resource implications for State permitting agencies associated with each of these options.

G. When Would a Phase III Existing Facility and New Offshore Oil and Gas Extraction Facility Be Required To Comply With Any New 316(b) Requirements?

If EPA were to promulgate today's proposed rule, the final rule would become effective sixty (60) days after the date of publication in the **Federal Register**. After the effective date of any such final regulation, existing manufacturers and new offshore oil and gas extraction Phase III facilities, including existing facilities not currently subject to cooling water intake requirements under 40 CFR 125, would need to comply when an NPDES permit containing requirements consistent with the final rule is issued to the facility (*see* § 125.100 and § 125.132). Under current NPDES program regulations, this will occur when a new NPDES permit is issued or when an existing NPDES permit is issued, reissued, or modified or revoked and reissued. As in Phase II, the proposed rule for Phase III existing facilities includes special provisions to allow sufficient time to complete a Comprehensive Demonstration Study during the first permit renewal following promulgation of the Phase III rule (*see* § 125.104(a)(2)(ii)).

A discussion of the timing of implementation of this proposed rule, if promulgated, is provided in section VII.

H. What Special Definitions Apply to This Proposal?

EPA is proposing specialized definitions to clarify which facilities are subject to national categorical requirements. For the new oil and gas extraction facility requirements in

[5] Unless otherwise noted, cost and benefit ranges reflect the use of alternative discount rates (3% and 7%) in annualized 2003 dollars.

Subpart N, EPA is proposing five new definitions to clarify those facilities subject to the requirements. These definitions are set forth in the proposed regulations at § 125.133 and include ''new offshore oil and gas extraction facilities,'' ''offshore liquified natural gas import terminals,'' ''seafood processing vessels,'' ''sea chest'' and ''fixed facility''). The remainder of the proposed definitions are the same as those found in the final Phase I regulations; however, not all of the definitions from Phase I regulations have been used as they are not all applicable to these proposed Subpart N regulations.

EPA is also proposing definitions for Phase III existing facilities in Subpart K at § 125.102. All of these definitions are borrowed from both Phase I and Phase II and remain unchanged, except for the cutoff date in the definition of ''existing facility'' for new versus existing offshore oil and gas extraction facilities. Similar to the definitions for subpart N described above, not all of the definitions from Phase II regulations have been used as they are not all applicable to these proposed Subpart K regulations.

EPA solicits comment on these regulatory definitions.

III. Summary of Data Collection Activities

For the Phase III proposed rule, EPA focused its data collection activities on section 316(b) survey data supplemented by available existing data sources including the data developed for the Phase I and Phase II rules.

A. Survey Questionnaires

As discussed in the preamble to the Phase II final rule (69 FR 41576), EPA's industry survey effort consisted of a two-phase process. EPA administered a screener questionnaire focused on nonutility and manufacturing facilities as the first phase of this data collection process. The screener questionnaire provides information on cooling water intake capacity, sources of the water, intake structure types, and technologies used to minimize adverse environmental impacts. It also provides data on facility and parent firm employee numbers and revenues. This information was used to design a sampling plan for the subsequent detailed questionnaire. Following the screener survey, the Agency administered either a short technical or a detailed questionnaire to utility, nonutility, and manufacturing facilities, as described below. The two-phase survey was designed to collect representative data from a sample group of those categories of facilities potentially subject to section 316(b) regulation for use in rule development.

In 1997, EPA estimated that over 400,000 facilities could potentially be subject to a cooling water intake regulation. Given the large number of facilities potentially subject to regulation, EPA decided to focus its data collection efforts on six industrial categories that, as a whole, were estimated to account for over 99 percent of all cooling water withdrawals. These six sectors were: Utility Steam Electric, Nonutility Steam Electric, Chemicals & Allied Products, Primary Metals Industries, Petroleum & Coal Products, and Paper & Allied Products. At the time of the survey, there were about 48,500 facilities in these six categories. EPA believes that this approach provided a sound basis for assessing best technologies available for minimizing adverse environmental impacts.

The screener survey focused on nonutility and manufacturing facilities. EPA developed the sample frame (list of facilities) for the screener questionnaire using public data sources as described in the Information Collection Request (DCN 3–3084-R2 in Docket W–00–03). Facilities chosen for the screener questionnaire represented a statistical sample of the entire universe of nonutility and manufacturing facilities potentially subject to cooling water intake regulations. EPA did not conduct a census of all facilities (*i.e.* send a survey to all facilities) for the screener questionnaire because of the burden associated with surveying a large number of facilities. Rather, EPA refined the industry data using industry-specific sources to develop sample frames and mailing lists. EPA believes the sample frame was sufficient to characterize the operations of each industrial category. EPA sent the screener questionnaire to 2600 facilities identified in the sample frame as follows: (1) All identified steam electric nonutility power producers, both industrial self-generators and nonindustrial generators (1050 facilities, of which 853 responded); and (2) a sample of manufacturers from the four non-steam electric industrial categories: paper and allied products, chemical and allied products, petroleum and coal products, and primary metals (1550 facilities, of which 1217 responded). EPA adjusted the sample frame for the screener questionnaire to account for several categories of non-respondents, including facilities with incorrect address information, facilities no longer in operation, and duplicate mailings. Through follow-up phone calls and mailings, EPA increased the response rate for the screener questionnaire to 95 percent. The screener questionnaire was not sent to utilities, all of which were believed to be identified accurately using the publicly-available data described above.

A sample of manufacturing and nonutility facilities identified as in-scope (subject to regulation) by the screener questionnaire and all utilities then were sent either a short technical or a detailed questionnaire. A total of 878 utility facilities, 343 nonutility facilities and 191 manufacturing facilities received one of the two questionnaires (short technical or detailed) during the second phase of the survey. For utilities, nonutilities, and other manufacturing facilities, EPA selected a random sample of these eligible facilities to receive a detailed questionnaire. The sample included 282 utility facilities and 181 nonutility facilities. All 191 manufacturing facilities received a detailed questionnaire. For nonutilities and utilities, those facilities not selected to receive a detailed questionnaire were sent a Short Technical Questionnaire. EPA's approach in selecting a sample involved the identification of population strata, the calculation of sample sizes based on desired levels of precision, and the random selection of sites given the sample size calculations within each stratum. More detail is provided in the report entitled ''Statistical Summary for Cooling Water Intakes Structures Surveys'' (*See* DCN 3–3077 in Docket W–00–03).

Five questionnaires were distributed to different industrial groups. They were: (1) Detailed Industry Questionnaire: Phase II Cooling Water Intake Structures—Traditional Steam Electric Utilities; (2) Short Technical Industry Questionnaire: Phase II Cooling Water Intake Structures—Traditional Steam Electric Utilities (sent to both utilities and nonutilities); (3) Detailed Industry Questionnaire: Phase II Cooling Water Intake Structures—Steam Electric Nonutility Power Producers; (4) Detailed Industry Questionnaire: Phase III Cooling Water Intake Structures—Manufacturers; and, (5) Watershed Case Study Short Questionnaire. The questionnaires provided EPA with technical and financial data necessary for developing this proposed regulation. Specific details about the questions may be found in EPA's Information Collection Request (DCN 3–3084–R2 in Docket W–00–03) and in the questionnaires (*see* DCN 3–0030 and 3–0031 in Docket W–00–03 and Docket for today's proposal); these documents are also available on EPA's Web site

(*http://www.epa.gov/waterscience/316b/question/*).

EPA also conducted outreach to industry groups, environmental groups, and other government entities in the development, testing, and refinement of a second round of surveys, the section 316(b) Phase III Industry Technical and Economic Questionnaires, which have been used as an additional source of data for the Phase III rule. The Phase III surveys, published in September 2003, were sent to offshore oil and gas extraction facilities and seafood processing vessels. Specific details about the questions may be found in EPA's Information Collection Request (DCN 7–0007) and in the questionnaires (*see* DCN 7–0008) in the Docket for today's proposal); these documents are also available on EPA's Web site (*http://www.epa.gov/waterscience/316b/question/*). In addition, EPA utilized a survey conducted by the International Association of Drilling Contractors (IADC) in 2003 to access technical data on cooling water use by offshore oil and gas extraction facilities, including fixed platforms and mobile units.

B. Existing Data Sources

EPA collected data from multiple sources, both public and proprietary, in order to compile an accurate profile of the potentially regulated community. EPA reviewed information collected by other Federal agencies, as well as data compiled by private companies. In those instances where databases are considered confidential, or where raw data was unavailable for review, EPA did not consider the information. Summaries of the reviewed data sources are listed below.

1. Electric Generators

EPA collected a substantial amount of data on the electric power generating industry in the course of the Phase I, II, and III rulemakings. For example, EPA used data from the Federal Energy Regulatory Commission (FERC) (Forms 1 and 1–F), the Energy Information Administration (EIA) (Forms EIA–412, –767, –860, –861, –867), the Rural Utility Service (RUS) (Form 12), as well as information from the U.S. Nuclear Regulatory Commission (NRC), the Utility Data Institute (UDI), and the Edison Electric Institute (EEI). For detailed information about these data sources, refer to the proposed rule for Phase II (67 FR 17131).

While electric power generators do not meet the proposed flow thresholds and are therefore not subject to Phase III national requirements (refer to section VI for further details), EPA did use the aforementioned data on electric power generators in reaching this decision. Data was used to assess, for example, the cooling water intake flows and the amount of electricity generated, and as part of the determination of economic impacts of the various compliance alternatives that EPA considered in developing the proposed rule.

2. Manufacturers

In order to identify potential entrainment impacts at facilities with a design intake flow below 50 MGD, EPA conducted a field study of six manufacturers in the Spring of 2002. This study was conducted in the mid-Atlantic region, with particular focus on the Delaware River and its tributaries. Sampling sites were selected for three freshwater and three tidal river facilities. EPA conducted two 4-day sampling events at each facility and conducted measurements of the following variables: site location and sampling point, facility intake flow rate, sampling pump volume, sampling time and duration and sample chain of custody. Additional physicochemical variables were measured, including the following: temperature, dissolved oxygen (DO), pH, and conductivity. Taxonomic identification was conducted for all organisms collected and results are provided in the *Data Report for Small Facility Ichthyoplankton Entrainment Sampling for the Development of the 316(b) Phase III Rule for Cooling Water Intake Structures* (EPA, 2003) (DCN 7–0009).

In mid-June 2003, in order to supplement the biological data used for estimating baseline impingement mortality and entrainment rates, EPA compiled a list of facilities who had responded in their industry questionnaire that they had conducted a biological study. Some of these facilities were then requested to provide EPA with copies of these studies. The first data collection effort focused on facilities that are located on an inland waterbody and have a high average daily intake flow. Preference was given to facilities located on Lake Michigan and the Columbia River, as these waterbodies (and more broadly, these regions of the country) were identified as having inadequate data for future analysis of Phase III impingement mortality and entrainment rates. The second data collection effort focused on facilities located in particular U.S. Fish and Wildlife Service fish regions to be used by EPA in calculation of benefits for the rule. The last data collection effort focused specifically on Phase III facilities. In total, 90 facilities were contacted and these contacts resulted in collection of 63 biological studies (33 of which were from Phase III facilities) for use in estimation of baseline impingement mortality and entrainment rates.

3. Offshore Oil and Gas Extraction Facilities and Seafood Processing Vessels

EPA conducted extensive research on the use of cooling water by offshore oil and gas extraction facilities and seafood processing vessels to determine whether these industry sectors would be subject to regulation under the Phase III rule. Information sources included industry surveys (one administered by EPA in conjunction with the International Association of Drilling Contractors (IADC) and another solely by EPA); industry databases and other publicly available information, and meetings with government and industry representatives. The survey efforts are described in section III.A above.

In April and May of 2003, EPA conducted site visits and field interviews at offshore oil and gas extraction facilities and seafood processing vessels to evaluate technologies in use for reducing impingement mortality and/or entrainment at these facilities. EPA employed the services of a specialized naval engineer to conduct these site visits and field interviews. Site visits were conducted at platforms and vessels. In addition, field interviews were conducted with industry personnel. The data collected from these visits and interviews included geographic data, intake design and impingement and entrainment technologies in place, impingement and entrainment problems encountered as well as any methods utilized in resolving such problems (*See* DCN 7–0010).

Sources used by EPA to characterize the offshore seafood processing industry included the following:

- U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition, January 2003, which included a list of U.S. FDA-European Union (EU) Exporters, Processing Vessels.
- Alaska Department of Fish and Game 2002 Intent to Operate Listing.
- Water Discharge Permits (PCS) database searches by SIC codes 2091, 2092 and 2077.
- Department of Transportation Maritime Administration (MARAD) Web site: *http://www.marad.dot.gov/publications/index.html* and *http://www.marad.dot.gov/Marad_Statistics/index.html*.
- U.S. Coast Guard Merchant Vessels of the United States database.

- U.S. Coast Guard PSIX/MSIS databases.
- National Transportation Safety Board database.
- U.S. Army Corps of Engineers, Navigation Data Center, Waterborne Commerce Statistics Center.
- The Alaska Department of Fish and Game Division of Commercial Fisheries Web site: *http://www.cf.adfg.state.ak.us*.
- The At-Sea Processors Association Web site: *http://www.atsea.org/*.
- EPA Region 10 Database of seafood processors permitted in Alaska.
- Technical Development Document (TDD) for the Uniform National Discharge Standards (UNDS) program (found at *http://unds.bah.com/TDD.pdf*) (Appendix A: Seawater Cooling Overboard Discharge Report).
- National Marine Fisheries Service Web site, Restricted Access Management Program, *http://www.fakr.noaa.gov/ram/default.htm*.
- National Marine Fisheries Services Web site, link to American Fisheries Act (AFA) permits: *http://www.fakr.noaa.gov/ram/afa.htm#list*.
- Several vessel operators, naval architects, engineers and regulators.

C. Data Provided to EPA by Industrial, Trade, Consulting, Scientific or Environmental Organizations or by the General Public

Since 1993, EPA has been developing cooling water regulations as part of a collaborative effort with industry and environmental stakeholders, other Federal agencies, the academic and scientific communities, and the general public. As a result, EPA has reviewed and considered the many documents, demonstration studies, scientific analyses, and historical perspectives offered in support of each phase of the regulatory process. For example, during the early stages of data gathering, EPA created an internal library of reference documents addressing cooling water intake structure issues. This library currently holds over 2,800 documents, many of which were referenced in the rulemaking process and are contained in the record (*see* the following paragraph for further information on the record). The library contains a thorough collection of a wide variety of documents, including over 80 section 316(b) demonstration documents, over 300 impingement and entrainment studies, over 100 population modeling studies, over 500 fish biology and stock assessment documents, over 350 biological studies commissioned by power generators, over 80 NPDES decisions and NPDES or SPDES-related documents, over 120 intake technology reports, over 10 databases on the electric power industry, and documents from interagency committees such as the Ohio River Valley Water Sanitation Commission (ORSANCO).

In addition, the record for the Phase I new facility rule contains nearly 1,000 documents (research articles, databases, legal references, memorandums, meeting notes, and other documents), consisting of approximately 47,000 pages of supporting material available for public review. And the record for the Phase II existing facility rule contains over 2600 additional documents, comprising approximately 125,000 pages of supporting material.

Finally, EPA has worked extensively with stakeholders from industry, public interest groups, State agencies, and other Federal agencies in the development of this proposed rule. These public participation activities have focused on various section 316(b) issues, including general issues, as well as issues relevant to development of the Phase II rule and issues relevant to this proposed Phase III rule. *See* section I.C.6 of this preamble for a discussion of key public participation activities.

IV. Overview of Facility Characteristics (Cooling Water Systems & Intake Structures) for Industries Potentially Subject to Proposed Rule

Today's proposed rule would apply national categorical requirements to two groups of facilities that use cooling water intake structures to withdraw water from waters of the U.S.: existing manufacturing and industrial facilities and new offshore oil and gas extraction facilities.

A. Overview of Potentially Regulated Phase III Universe

EPA's data collection efforts largely focused on five industrial sectors: small flow electric power generators (both utilities and nonutilities withdrawing less than 50 MGD); chemicals and allied products (SIC Major Group 28); primary metals industries (SIC Major Group 33); paper and allied products (SIC Major Group 26); and petroleum and coal products (SIC Major Group 29). The latter four sectors use a significant portion of the cooling water withdrawn among all manufacturing industries. EPA also identified other industry sectors that use cooling water including: transportation equipment (SIC Major Group 37); lumber and wood products (SIC Major Group 24); rubber and plastics products (SIC Major Group 30); food and kindred products (SIC Major Group 20); tobacco products (SIC Major Group 21); and machinery (SIC Major Group 35) (see DCN 7–0011). A more comprehensive list of industries that use cooling water and their NAICS and SIC Codes can be found in section A of the Supplementary Information. Although EPA's survey data collection efforts were not designed to collect data from industries other than the five listed above, data were collected from the following industries: food processing; aircraft engines and engine parts; cutlery; sawmills and planing mills; finishers of broad woven fabrics of cotton; potash, soda and borate minerals; iron ores; and sugarcane and sugar beets. These data from other industries, while not a statistically derived sample, confirm that the five primary industry sectors discussed above account for the vast majority of Phase III cooling water use. The data also suggest that the intake structure design and construction at these industries were substantially similar to the industries for which EPA did collect data.

Of the estimated 683 manufacturing and electric generator facilities (survey weighted estimate, as described in the *Technical Development Document* EPA–821–R–04–015, DCN 7–0004) within the Phase III universe,[6] approximately 225 (33 percent) belong to the pulp and paper sector, 185 (27 percent) belong to the chemical sector, 88 (13 percent) belong to the metals sector, and 39 (6 percent) belong to the petroleum sector. EPA also surveyed 29 facilities in other industry sectors (discussed above, all of which are potentially subject to the Phase III rule) in the detailed questionnaire, and those data are also being considered in today's proposed rule. In addition, an estimated 117 (17 percent) electric generating facilities are included within the Phase III universe.

The information below is generally based on data collected from the Short Technical Industry Questionnaire, the Detailed Industry Questionnaire, and the Phase III Industry Technical and Economic Questionnaires. Additional detail discussing the entire Phase III universe as well as facilities subject to the uniform national standards and facilities subject to permitting based on best professional judgment can be found in the Technical Development Document.

As explained in section V of this preamble, there are five main categories of surface water used as sources of cooling water. The source of surface water withdrawn for cooling is an

[6] The entire Phase III universe includes facilities with a design intake flow greater than 2 MGD which use at least 25 percent of the water withdrawn exclusively for cooling, and are not covered by Phase II. Offshore oil and gas extraction facilities are not included in this estimate.

important factor in determining potential environmental impacts. An estimated 11 (2 percent) facilities withdraw cooling water from an ocean; an estimated 39 (6 percent) facilities withdraw cooling water from an estuary or tidal river; an estimated 496 (73 percent) facilities withdraw cooling water from a freshwater stream or river; an estimated 60 (9 percent) facilities withdraw cooling water from a lake or reservoir; and an estimated 77 (11 percent) facilities withdraw cooling water from one of the Great Lakes. EPA estimates a total design intake flow of 40,441 MGD and total actual intake flow of 21,624 MGD for the Phase III universe.

Of the facilities within the Phase III universe, 303 (44 percent) employ once-through cooling systems, 198 (29 percent) use closed-cycle recirculating cooling systems, 121 (18 percent) use ''combination'' systems, and 61 (9 percent) use an ''other'' type of system. An estimated 286 (42 percent) facilities have installed a cooling tower. Note that not all facilities that have installed a cooling tower are classified as using closed-cycle recirculating cooling systems, as some facilities with multiple cooling water systems may be ''combination'' systems that employ both closed-cycle and once-through cooling. Facilities may also list ''helper'' cooling towers, which are generally used to mitigate discharge temperatures and do not affect intake flows. Since facilities may have more than one cooling water system, these estimates are based on the predominant cooling water system at each facility.

Facilities within this universe also may have more than one cooling water intake structure configuration. Therefore, in providing the information on intake structures, a facility may be counted multiple times (as many times as it has distinct cooling water intake structure configurations). Thus, of the facilities within the Phase III universe, 683 facilities represent an estimated 747 total cooling water intake structure configurations. Of these, an estimated 359 (48 percent) have a shoreline intake, 216 (29 percent) have a submerged offshore intake, 123 (16 percent) withdraw cooling water through a canal or channel, 49 (7 percent) have an intake situated in a bay or cove, and 47 (6 percent) are estimated to have some other type of intake or provided no information.

B. Existing Manufacturers and Industrial Facilities Potentially Subject to Proposed National Requirements

This section presents the number of facilities that would be potentially subject to uniform national performance standards under each of the three co-proposed options. *See* section VI of this preamble and Chapter 4 of the Technical Development Document for details on the other options considered but not presented as part of today's proposal. Exhibit IV–1 provides the number of existing facilities by design intake flow and waterbody type. Throughout the rest of this section, tabulations of less than five facilities are combined to prevent disclosure of an individual facility's information.

EXHIBIT IV–1.—TOTAL NUMBER OF PHASE III MANUFACTURING FACILITIES POTENTIALLY SUBJECT TO THE REGULATIONS BY DESIGN INTAKE FLOW AND WATERBODY TYPE

Facility design intake flow	Waterbody		
	Freshwater rivers and streams, lakes, and reservoirs	Oceans, estuaries, tidal rivers and streams, and Great Lakes	All waterbodies
2 MGD or greater [1]	556	127	683
20 MGD or greater [1]	302	92	394
50 MGD or greater [2]	103	52	155
100 MGD or greater [2]	47	26	73
200 MGD or greater [2]	16	15	31

[1] Includes those electric generating facilities defined as part of the Phase III universe.
[2] Only includes manufacturing facilities.

1. National Requirements for Facilities With a Design Intake Flow of 50 MGD and Above

EPA's 50 MGD option would require an estimated 155 facilities to meet the uniform national standards that implement section 316(b) (facilities with a design intake flow of 50 MGD and above and meeting applicability criteria at § 125.101). These facilities are comprised of an estimated 56 (36 percent) within the chemical sector, 42 (27 percent) within the pulp and paper sector, 30 (19 percent) within the metals sector, 17 (11 percent) within the petroleum sector, and an estimated total of 10 facilities (7 percent) within the ''other'' category; no seafood processing vessels would meet the applicability criteria at § 125.101.

An estimated 6 (4 percent) facilities withdraw cooling water from an ocean; an estimated 15 (10 percent) facilities withdraw cooling water from an estuary or tidal river; an estimated 93 (60 percent) facilities withdraw cooling water from a freshwater stream or river; an estimated 10 (6 percent) facilities withdraw cooling water from a lake or reservoir; and an estimated 31 (20 percent) facilities withdraw from one of the Great Lakes.

EPA has estimated that these 155 facilities possess a total design intake flow of 30,136 MGD and an actual intake flow of 16,582 MGD.

Further, of the cooling water system types in use at these 155 facilities, 68 (44 percent) of these systems are once-through cooling systems, 6 (4 percent) are closed-cycle recirculating cooling systems, 56 (36 percent) are ''combination'' systems, and 25 (16 percent) use an ''other'' type of system. An estimated 52 (33 percent) facilities have installed a cooling tower. As noted above, not all facilities that have installed a cooling tower are classified as closed-cycle recirculating cooling system.

These 155 facilities possess an estimated 211 total cooling water intake structure configurations. Of these, an estimated 46 (23 percent) facilities withdraw cooling water through a canal or channel, 17 (11 percent) have an intake situated in a bay or cove, 89 (59 percent) have a shoreline intake, 31 (20 percent) have a submerged offshore intake, and 28 (5 percent) are estimated to have some other type of intake or provide no information.

2. National Requirements for Facilities With a Design Intake Flow of 200 MGD and Above

EPA's 200 MGD option would require an estimated 31 facilities to meet the uniform national standards that implement section 316(b) (facilities with a design intake flow of 200 MGD and above and meeting applicability criteria at § 125.101). These facilities are comprised of an estimated 15 (48 percent) within the metals sector, 7 (23 percent) within the chemical sector, and 9 (29 percent) within the petroleum sector, the pulp and paper sector, or the ''other'' industries category.

An estimated 5 (16 percent) facilities withdraw cooling water from an estuary or tidal river; an estimated 16 (50 percent) facilities withdraw cooling water from a freshwater stream or river, lake, or reservoir; and an estimated 10 (32 percent) facilities withdraw from one of the Great Lakes. EPA estimates that there are no manufacturing facilities with a design intake flow of 200 MGD or greater that withdraw from an ocean.

EPA has estimated that these 31 facilities possess a total design intake flow of 18,340 MGD and an actual intake flow of 11,472 MGD.

Further, of the cooling water system types in use at these 31 facilities, 17 (55 percent) of these systems are once-through cooling systems, and 14 (45 percent) are ''combination'' or ''other'' systems. An estimated 10 (32 percent) facilities have installed a cooling tower or closed-cycle recirculating system.

These 31 facilities possess an estimated 70 total cooling water intake structure configurations. Of these, an estimated 16 (23 percent) facilities withdraw cooling water through a canal or channel, 24 (34 percent) have a shoreline intake, and 30 (43 percent) have a submerged offshore intake.

3. National Requirements for Coastal and Great Lakes Facilities With a Design Intake Flow of 100 MGD and Above

EPA's third proposed option would establish national requirements for facilities with 100 MGD or more design intake flows when the intake is on coastal waters (including oceans, tidal rivers and streams, and estuaries) or one of the Great Lakes. This option would require an estimated 26 facilities to meet the uniform national standards. These facilities are comprised of an estimated 12 (46 percent) within the metals sector, 7 (27 percent) within the chemical sector, and the remaining 7 (27 percent) within the pulp and paper sector, the petroleum sector, or the ''other'' industries. EPA estimated that these 26 facilities possess a total design intake flow of 7,661 MGD and actual intake flow of 4,753 MGD.

Further, of the predominant system types in use at these 26 facilities, 13 (50 percent) of these systems are once-through cooling systems. The other estimated 13 facilities use a combination cooling system and have installed a cooling tower. These 26 facilities possess an estimated 47 total cooling water intake structure configurations. Of these, an estimated 11 (23.4 percent) facilities withdraw cooling water through a canal or channel, 21 (44.7 percent) have a shoreline intake, and 15 (31.9 percent) have a submerged offshore intake.

C. New Offshore Oil and Gas Extraction Facilities Subject to Proposed National Requirements

Today's proposed rule would also apply national requirements to new offshore (offshore includes coastal) oil and gas extraction facilities. EPA is presently considering new facilities within the offshore oil and gas extraction industry as classified under SIC Major Group 13. EPA projects that there will be an estimated 124 new offshore oil and gas extraction facilities over the next 20 years. Most of these facilities will withdraw less than 50 MGD estimated design intake flow and will include both mobile offshore drilling units (MODUs) and deepwater platforms in the Gulf of Mexico and Alaska. Only three new MODUs are projected to have a design intake flow of greater than 50 MGD within the period of analysis. EPA's projection of new oil and gas extraction facilities is based on historical refurbishment of old rigs including MMS data on new platform installations over the last 10 years. *See* Part C of the EA for more information. Note most new offshore and coastal oil and gas extraction facilities to which today's proposed rule would apply would not be operating in estuaries, except for those operating in Cook Inlet.

V. Environmental Impacts Associated With Cooling Water Intake Structures

Through the Phase III rulemaking, EPA intends to minimize the adverse environmental impacts of cooling water intake structures by reducing the number of aquatic organisms lost as a result of water withdrawals associated with these structures or through restoration measures that compensate for these losses. In the Phase I rule for new facilities and in the Phase II rule for certain existing facilities, EPA provided an overview of the magnitude and type of environmental impacts associated with cooling water intake structures, including several illustrative examples of documented environmental impacts at existing facilities (*see* 65 FR 49071–4; 66 FR 65262–5; 67 FR 17136–40; and 69 FR 41587–88).

For the same reasons set forth in the preamble to the rules for Phase I and Phase II facilities (66 FR 65256, 65291–65297 and 69 FR 41586–90), EPA has determined that there are multiple types of undesirable and unacceptable environmental impacts that may be associated with Phase III facilities, depending on conditions at the individual site. These types of impacts include entrainment and impingement which can contribute to reductions of threatened and endangered species; and ecologically critical aquatic organisms, including important elements of the food chain; diminishment of a population's compensatory reserve; losses to populations, including reductions of indigenous species populations, commercial and recreational fisheries; and stresses to overall communities and ecosystems as evidenced by reductions in diversity or other changes in system structure and function. Based on the analyses in and for the same reasons set forth in the preambles to the Phase I rule (66 FR 65256, 65291–65297) and Phase II rule (69 FR 41598–41601), EPA has selected reductions in impingement mortality and entrainment as a quick, certain, and consistent metric for comparing facility performance to applicable requirements for Phase III facilities. Further, EPA considered the non-water quality environmental impacts for this rule (*e.g.*, impacts on energy use and associated increases in emissions) and found them to be acceptable at a national level. This section describes the environmental impacts associated with cooling water withdrawals and why they are of concern to the Agency.

Impingement takes place when organisms are trapped against cooling water intake screens by the force of the water being drawn through the cooling water intake structure. The velocity of the water withdrawal by the cooling water intake structure may prevent proper gill movement, remove fish scales, and cause other physical harm or death of affected organisms through exhaustion, starvation, asphyxiation, and descaling. Death from impingement (''impingement mortality'') can occur immediately or subsequently as an individual succumbs to physical damage upon its return to the waterbody.

Entrainment occurs when organisms are drawn through the cooling water intake structure into the cooling system.

Organisms that become entrained are typically relatively small, aquatic organisms, including early life stages of fish and shellfish. Many of these small fragile organisms serve as prey for larger organisms higher on the food chain which are commercially and recreationally desirable species. As entrained organisms pass through a facility's cooling system they may be subject to mechanical, thermal, and at times, chemical stress. Sources of such stress include physical impacts in the pumps and condenser tubing, pressure changes caused by diversion of the cooling water into the plant or by the hydraulic effects of the condensers, sheer stress, thermal shock in the condenser and discharge tunnel, and chemical toxic effects from antifouling agents such as chlorine. Similar to impingement mortality, death from entrainment can occur immediately or subsequently as the individual succumbs to the damage from the stresses encountered as it passed through the cooling water system once it is discharged back into the waterbody.

EPA estimates that existing Phase III facilities withdraw, on average, approximately 23,000 million gallons a day from waters of the United States.[7] [8] The withdrawal of such large quantities of water has the potential to affect large quantities of aquatic organisms including phytoplankton (tiny, freefloating photosynthetic organisms suspended in the water column), zooplankton (small aquatic animals, including fish eggs and larvae, that may consume phytoplankton and other zooplankton), fish, and shellfish. Aquatic organisms drawn into cooling water intake structures are either impinged on components of the cooling water intake structure or entrained in the cooling water system itself. Other organisms, including reptiles, birds, and mammals are also sometimes drawn into cooling water intake structures.

The environmental impacts attributable to impingement mortality and entrainment at individual facilities include losses of early life stages of fish and shellfish, reductions in forage species, and decreased recreational and commercial fishery landings. EPA estimates that cooling water intake structures potentially within the scope of today's rule and with a cooling water intake designed to take in greater than 2 MGD of water kill more than 120 million age 1 equivalent fish annually through impingement and entrainment. Expressing impingement mortality and entrainment losses as age 1 equivalents is an accepted method for converting losses of all life stages into individuals of an equivalent age and provides a standard metric for comparing losses among species, years, and facilities. Although the number of age 1 equivalent fish killed by impingement and entrainment is large, precise quantification of the nature and extent of impacts to populations and ecosystems is difficult due in part to the complexity of population dynamics and the physical, chemical, and biological processes of ecosystems. While it is generally accepted as a simple and transparent method for modeling losses, the proportional methodology that EPA uses to estimate impingement mortality and entrainment nationwide involves uncertainties that may result in under or over estimating actual impingement mortality and entrainment rates.[9]

Decreased numbers of aquatic organisms can disrupt aquatic food webs and alter species composition and overall levels of biodiversity. For example, a model that examined the effect of large entrainment losses of forage fish, such as bay anchovy, predicted subsequent reductions in predator populations (including commercially and recreationally important species such as striped bass, weakfish, and blue fish) as high as 25 percent.[10] This is because forage species, which comprise a majority of entrainment losses at many facilities, are often a primary food source for predator species.

EPA is also concerned about the potential impacts of cooling water intake structures located in or near habitat areas that support threatened, endangered, or other species of concern (those species that might be in need of conservation actions, but are not currently listed as threatened or endangered under State or Federal law).[11] In the San Francisco Bay-Delta Estuary, California, in the vicinity of the Pittsburg and Contra Costa Power Plants several fish species (*e.g.*, Delta smelt, Sacramento splittail, chinook salmon, and steelhead) are now considered threatened or endangered by State and/or Federal authorities. EPA evaluated facility data on impingement mortality and entrainment rates for these species and estimated that potential losses of special status fish species at the two facilities may average 8,386 age 1 equivalents per year resulting from impingement and 169 age 1 equivalents per year due to entrainment.[12] In another example, EPA is aware that from 1976 to 1994, approximately 3,200 threatened or endangered sea turtles entered enclosed cooling water intake canals at the St. Lucie Nuclear Generating Plant in Florida.[13] The facility developed a capture-and-release program in response to these events. Most of the entrapped turtles were captured and released alive; however, approximately 160 turtles did not survive. An incidental take limit established by NOAA Fisheries in a 2001 biological opinion for this facility has been set at no more than 1,000 sea turtles captured in the intake, with less than one percent killed or injured as a result of plant operations.[14] Although the extent to which threatened, endangered, and other special status species are taken by cooling water intake structures more generally is yet to be determined, EPA is concerned about potential impacts to such species.

EPA is addressing the universe of existing facilities through two separate rulemakings. The Phase II final rule addressed power generation facilities with cooling water intake structures designed to take in water flows greater than or equal to 50 million gallons a day (MGD). For today's proposed rulemaking, EPA evaluated impacts from the remaining power generation facilities (those with cooling water intake structures designed to withdraw greater than 2 MGD and less than 50 MGD) and from manufacturing facilities withdrawing greater than 2 MGD. EPA divided the universe of existing facilities in this way in part because EPA initially had limited data on Phase III facilities with design capacities less than 50 MGD. Dividing the universe of existing facilities provided EPA with an

[7] EPA 1999. Detailed Industry Questionnaires: Phase II Cooling Water Intake Structures & Watershed Case Study Short Questionnaire. U.S. Environmental Protection Agency, Office of Wastewater Management, Washington, DC. OMB Control No. 2040–0213.

[8] EPA 2003. Industry Technical Questionnaire: Phase III Cooling Water Intake Structures. Offshore and Coastal Oil and Gas Extraction Facilities. U.S. Environmental Protection Agency, Office of Science and Technology, Washington DC. OMB Control No. 2030–0213.

[9] For more information, please *see* Chapter A2 of Part A of the Regional Analysis Document.

[10] Summers, J.K. 1989. Simulating the indirect effects of power plant entrainment losses on an estuarine ecosystem. Ecological Modeling, 49: 31–47.

[11] For more information, please *see* Chapter A9 of Part A of the Regional Analysis Document.

[12] Impingement and entrainment data were obtained from the 2000 Draft Habitat Conservation Plan for the Pittsburg and Contra Costa facilities. Please *see* EPA's Regional Studies for the Final Section 316(b) Phase II Existing Facilities Rule for detailed information on EPA's evaluation of impingement and entrainment at these facilities.

[13] Florida Power and Light Company. 1995. Assessment of the impacts at the St. Lucie Nuclear Generating Plant on sea turtle species found in the inshore waters of Florida.

[14] Florida Power and Light Company. 2002. Florida Power & Light Company St. Lucie Plant Annual Environmental Operating Report 2002.

opportunity to gather more information on Phase III facilities.

Though the magnitude of impacts EPA has quantified from the universe of Phase III facilities is substantially smaller than the magnitude of impacts EPA has quantified from the universe of Phase II facilities, the information EPA has gathered on individual Phase III facilities indicates that the types of impacts that large individual facilities have on aquatic organisms can be similar to individual Phase II facilities' impacts.[15] Like Phase II facilities, Phase III facilities withdraw water from all waterbody types: lake, reservoir, Great Lake, freshwater river and stream, tidal river, estuary, and ocean environments. A smaller percentage of the overall cooling water flow withdrawn by Phase III facilities comes from tidal river, estuary and ocean environments, however, which are some of the most sensitive waterbodies. Phase III facilities also reside in many of the same geographic areas of the country and on many of the same waterbodies as Phase II facilities.

Information available to the Agency also indicates that the range of configurations of Phase III cooling water intake structures is similar to that of Phase II intakes (*see* section VI), and that their size ranges broadly overlap (in terms of both design capacity and actual intake flow). The majority of facilities evaluated as part of the Phase III rulemaking, have cooling water intake structures designed to take in less than 50 MGD. However, the majority of total cooling water intake volume at Phase III facilities is associated with facilities designed to withdraw 50 MGD or more. The ten largest Phase III facilities have intakes designed to take in more than 500 MGD. Two of these facilities have cooling water intakes designed to take in more than 1,000 MGD. In Phase II, there were 257 facilities with cooling water intakes designed to take in more than 500 MGD and 112 cooling water intakes designed to take in more than 1,000 MGD.

The universe of Phase III facilities also differs from that of Phase II facilities in that it includes oil and gas extraction facilities operating in offshore marine environments. EPA knows of no studies that examine actual impingement mortality and entrainment by offshore oil and gas extraction facilities. However, offshore marine environments provide habitat for a number of species of fish, shellfish, and other aquatic organisms. Many species have life stages that are small and planktonic or of minimal swimming ability and are therefore vulnerable to entrainment by cooling water intake structures. Larger life stages are potentially vulnerable to impingement. Both types of organisms are found in the offshore marine environment and thus may be susceptible to impingement mortality and entrainment by offshore oil and gas extraction facilities. The densities of organisms in the vicinity of these facilities relative to densities in estuaries and other nearshore areas is not well characterized.

Offshore oil and gas extraction facilities have also been shown to attract and concentrate aquatic organisms in the immediate vicinity of the underwater portions of their structure. A variety of species of pelagic fish have been found to gather within relatively short time frames around the underwater portion of offshore oil and gas extraction facilities. If a facility remains in one place for a sufficient length of time, other species of aquatic organisms take up residence directly upon the underwater structure and form reef-like communities that support additional species of fish and shellfish. The increased number of organisms near the underwater portion of facilities where cooling water intake structures are located increases the potential for impingement mortality and entrainment of those organisms. The extent to which the increased numbers of aquatic organisms represents an overall increase in organism populations, rather than a simple concentration of organisms from surrounding areas, is not known. (For additional information, *see* DCN 7–0013.)

The Minerals Management Service (MMS) did attempt to estimate potential population level impacts from impingement mortality and entrainment associated with the future operation of the Liberty Island project located in the Beaufort Sea in Alaska. The final Environmental Impact Statement for the project states that the proposed seawater intake structure will likely harm or kill some young-of-the-year arctic cisco during the summer migration period and some eggs and fry of other species living in the immediate vicinity of the intake. MMS estimated that less than 1% of all arctic cisco in the Liberty Island area were likely to be harmed or killed by the intake structure and that there would not be a measurable effect on the young-of-the-year cisco in the migration corridor. However, MMS also did not expect measurable effects on populations of other fish species, including salmon, because of the widespread and low density distribution of those species' eggs and fry. Essential fish habitat for salmon will be adversely affected according to MMS because it is expected that prey species of zooplankton and fish in their early life stages (juveniles, eggs, and larvae) could be killed in the intake (*see* Section A of the Regional Study report).

EPA's analyses indicate that, on a national basis, Phase II existing facilities have a total actual cooling water intake flow (214,000 million gallons a day) greater than that of Phase III existing facilities (23,000 million gallons a day). As discussed in the preamble to the Phase II final rule (69 FR 41612), information in the record contains evidence to support the proposition that, in a given aquatic environment, entrainment is related to flow (see DCN 2–013L–R15 and 2–013) while impingement is related to a combination of flow, intake velocity, and fish swim speed (*see* DCN 2–029). Larger withdrawals of water may result in commensurately greater levels of entrainment because the eggs and larvae of some aquatic species are free-floating and may be drawn with the flow of cooling water into an intake structure. Impingement rates are also influenced by swim speeds of affected species and intake velocity. As described in section IX, the Agency estimates that 120 million age 1 equivalent fish are impinged and entrained annually by the universe of Phase III facilities. This number is lower than the 3.4 billion age 1 equivalent fish the Agency estimated to be impinged and entrained annually by Phase II facilities (69 FR 41656). The lower total flow partially explains why the impacts EPA quantified for Phase III facilities are lower than those EPA quantified for Phase II facilities. In addition, based on the studies EPA was able to collect from Phase II and Phase III facilities, even on a flow-weighted basis the number of organisms impinged and entrained by Phase III facilities is approximately one third of the number of organisms impinged and entrained by Phase II facilities.

The following discussion refers to studies from Phase II facilities which have been extensively studied in order to illustrate environmental impacts associated with cooling water intake structures. Because of the basic similarities in nature among Phase II and Phase III facilities, the Agency believes these case studies are useful for understanding the types of environmental impacts that may result from cooling water intake structures at Phase III facilities. EPA notes that Phase II facilities as a group withdraw more

[15] EPA 1999. Detailed Industry Questionnaires: Phase II Cooling Water Intake Structures & Watershed Case Study Short Questionnaire. U.S. Environmental Protection Agency, Office of Wastewater Management, Washington, DC. OMB Control No. 2040–0213.

cooling water than the Phase III facilities as a group and requests comment on the relevance of these Phase II facility studies for the Phase III rulemaking. EPA also requests any case studies or other available data on environmental impacts from Phase III facilities.

Examples of Environmental Impacts Caused by Phase II Cooling Water Intake Structures

1. Hudson River

The power generation facilities on the Hudson River in New York are some of the most extensively studied in the nation. The fish populations in the Hudson River have also been studied extensively to measure the impacts of these power plants. Studies of entrainment at five Hudson River power plants during the 1980s predicted year-class reductions ranging from six percent to 79 percent, depending on the fish species.[16] The combined design intake flow capacity of these five facilities is greater than 6,500 million gallons per day. The New York State Department of Environmental Conservation (NYSDEC) concluded that any ''compensatory responses to this level of power plant mortality could seriously deplete any resilience or compensatory capacity of the species needed to survive unfavorable environmental conditions.''[17]

The Final Environmental Impact Statement (FEIS) prepared for these three of these five facilities concludes that impacts are associated with the power plants and notes that these impacts are more like habitat degradation than the ''selective cropping'' of fish that occurs during regulated fishing because the entire community is impacted rather than specific species higher on the food chain.[18] The FEIS estimates, from samples collected between 1981 and 1987, that the average annual entrainment losses from these three facilities includes 16.9 million American shad, 303.4 million striped bass, 409.6 million bay anchovy, 468 million white perch, and 826.2 million river herring.[19] In addition, related studies have found a small long-term decline in both species richness and diversity within the resident fish community.[20]

The Hudson River, like many waterbodies in the nation, has undergone many changes in the past few decades. These changes, which have affected fish populations either positively or negatively, include improvements to water quality as a result of upgrades to sewage treatment plants, invasions by exotic species such as zebra mussels, chemical contamination by toxins such as PCBs and heavy metals, global climate shifts such as increases in annual mean temperatures and higher frequencies of extreme weather events (e.g., the El Niño-Southern Oscillation), and strict management of individual species stocks such as striped bass.[21] In addition, there are dramatic natural changes in fish populations on an annual basis and in the long term due to natural phenomena because the Hudson River, like many waterbodies, is a dynamic system with many fundamental, fluctuating environmental parameters-such as flow, temperature, salinity, dissolved oxygen, nutrients, and disease-that cause natural variation in fish populations each year.[22] The existence of these interacting variables makes it difficult to determine the impact of impingement and entrainment losses on a population's relative health. Nonetheless, as described later in this section, EPA is concerned about the potential for cumulative impacts resulting from multiple facility intakes that collectively impinge and/or entrain aquatic organisms within a specific waterbody.

2. Mount Hope Bay

Environmental impacts were also studied in another recent permit reissuance for the Brayton Point Station in Somerset, Massachusetts, where EPA is the permitting authority. EPA determined that, among other things, the facility's cooling water system had contributed to the collapse of the fishery and inhibited its recovery despite stricter commercial and recreational fishing limits and improved water quality due to sewage treatment upgrades. The facility currently withdraws nearly one billion gallons of water each day (1,000 MGD) and the average annual losses of aquatic organisms due to impingement and entrainment are estimated in the billions, including, among other species, 251 million winter flounder, 375 million windowpane flounder, 3.5 billion tautog and 11.8 billion bay anchovy.[23] A dramatic change in the fish populations in Mount Hope Bay is apparent after 1984 with finfish abundance decline by more than 87 percent, which coincides with a 45 percent increase in cooling water withdrawal from the bay due to the modification of Unit 4 from a closed-cycle recirculating system to a once-through cooling water system and a similar increase in the facility's thermal discharge.[24] [25] The relative contributions of cooling water withdrawal and increased thermal discharge to the observed population decline is not known, and some of decline may be due to factors other than cooling water. However, the downward trend of several species of finfish abundance in Mount Hope Bay is significantly greater than declines for the same species in adjacent Narragansett Bay that is not influenced by the operation of Brayton Point Station.[26] Despite fishing restrictions, fish stocks have not recovered.

3. Southern California Bight

At the San Onofre Nuclear Generating Station (SONGS) (3,300 MGD design intake capacity), in a normal (non-El Niño) year, an estimated 57 tons of fish were killed per year when all units were in operation.[27] The amount lost per year included approximately 350,000 juveniles of white croaker, a popular

[16] Boreman J. and P. Goodyear. 1988. Estimates of entrainment mortality for striped bass and other fish species inhabiting the Hudson River Estuary. American Fisheries Society Monograph 4:152–160.

[17] New York State Department of Environmental Conservation (NYSDEC). 2000. Internal memorandum provided to the U.S. EPA on NYDECs position on SPDES permit renewals for Roseton, Bowline Point 1 & 2, and Indian Point 2 & 3 generating stations.

[18] New York State Department of Environmental Conservation (NYSDEC). 2003. Final Environmental Impact Statement: Concerning the Applications to Renew NYSPDES Permits for the Roseton 1 & 2, Bowling 1 & 2 and Indian Point 2 & 3 Steam Electric Generating Stations, Orange, Rockland and Westchester Counties.

[19] Ibid.

[20] Henderson, P.A. and R.M. Seaby. 2000. Technical comments on the Draft Environmental Impact Statement for the State Pollution Discharge Elimination System Permit Renewal for Bowline Point 1 & 2, Indian Point 2 & 3, and Roseton 1 & 2 Steam Generating Stations. Pisces Conservation Ltd.

[21] Ibid.

[22] New York State Department of Environmental Conservation (NYSDEC). 2003. Final Environmental Impact Statement: Concerning the Applications to Renew NYSPDES Permits for the Roseton 1 & 2, Bowling 1 & 2 and Indian Point 2 & 3 Steam Electric Generating Stations, Orange, Rockland and Westchester Counties.

[23] Brayton Point Station, Somerset, MA. Final National Pollutant Discharge Elimination System (NPDES) Permit: Fact Sheet. October 2003.

[24] Ibid.

[25] Gibson, M. 1995 (revised 1996). Comparison of trends in the finfish assemblages of Mt. Hope Bay and Narragansett Bay in relation to operations fo the New England Power Brayton Point station. Rhode Island Division of Fish and Wildlife, Marine Fisheries Office.

[26] EPA-New England. 2002. Clean Water Act NPDES Permitting Determinations for Thermal Discharge and Cooling Water Intake from Brayton Point Station in Somerset, MA (NPDES Permit No. MA 0003654), July 22, 2002.

[27] Murdoch, W.W., R.C. Fay, and B.J. Mechalas. 1989. Final Report of the Marine Review Committee to the California Coastal Commission. August 1989, MRC Document No. 89–02.

sport fish; this number represents 33,000 adult equivalents or 3.5 tons of adult fish. In shallow water, densities of queenfish and white croaker decreased 60 percent within one kilometer of SONGS and 35 percent within three kilometers from SONGS as compared to densities prior to facility operations. Densities of local midwater fish decreased 50 to 70 percent within three kilometers of the facility. In contrast, relative abundances of some bottom-dwelling species in the same areas were higher because of the enriched nature of the SONGS discharge, which in turn supported elevated numbers of prey items for bottom-dwelling fish.

4. Missouri River

Facilities sited on waterbodies previously impaired by anthropogenic activities such as channelization can demonstrate the potential for reduced entrainment and impingement losses associated with cooling water intake structures. The Neal Generating Complex facility, located near Sioux City, Iowa, on the Missouri River is coal-fired and utilizes once-through cooling systems. According to a ten year study conducted from 1972–82, the Missouri River aquatic environment near the Neal complex was previously heavily impacted by channelization and very high flow rates meant to enhance barge traffic and navigation.[28] These anthropogenic changes to the natural river system resulted in significant losses of fish habitat. At this facility, there was found to be little impingement mortality and entrainment by cooling water intake structures.

Studies like those described in this section provide only a partial picture of the range of environmental impacts associated with cooling water intake structures. Although numerous studies were conducted to determine the environmental impacts caused by impingement mortality and entrainment at existing facilities, many of them are based on limited data that were collected more than 25 years ago. EPA's review of available facility impingement and entrainment studies identified a substantial number of serious study design limitations, including data collections for only one to two years or limited to one season or for a subset of the affected species; limited taxonomic detail (*i.e.*, egg and larval losses not identified to the species level); a general lack of statistical information such as inclusion of variance measures for impingement and entrainment estimates; and the lack of standard methods and metrics for quantifying impingement mortality and entrainment, which limits the potential for comparing impacts among species, years, sites, and technologies and for evaluating cumulative impacts across multiple facilities. Further, in many cases it is likely that facility operating conditions and/or the state of the waterbody itself has changed since these studies were conducted. Finally, the methods for monitoring impingement and entrainment used in the 1970s and 1980s, when most section 316(b) evaluations were performed, were often inconsistent or incomplete, making quantification of impacts difficult. Recent advances in environmental assessment techniques provide new and, in some cases, better tools for monitoring impingement and entrainment and quantifying the current magnitude of the impacts.[29] [30] It is difficult to predict the effects of these study limitations on the impacts estimates, specifically whether they have led to an overestimate or underestimate of impacts. The studies do show, however, that the nature and magnitude of impacts are highly case specific.

EPA is also concerned about the potential for cumulative impacts related to cooling water withdrawal. Cumulative impacts may result from: (1) Multiple facility intakes impinging and/or entraining aquatic organisms within a specific waterbody, watershed, or along the migratory pathway of specific species; (2) the existence of multiple stressors within a waterbody/watershed, including cooling water intake structures withdrawals; and (3) repeated, long-term occurrences of impingement and/or entrainment losses that may result in the diminishment of the compensatory reserve of a particular fishery stock.

Historically, environmental impacts related to cooling water intake structures have been evaluated on a facility-by-facility basis. These historical evaluations do not consider the potential for a fish or shellfish species to be concomitantly impacted by cooling water intake structures belonging to other facilities that are located within the same waterbody or watershed in which the species resides or along the coastal migratory route of a particular species. Based on EPA's estimation of national impacts from Phase II and Phase III facilities, Phase II facilities would contribute a greater level of stress to a national measurement of cumulative stress than would the universe of Phase III facilities. However, the potential cumulative effects on a species or ecosystem of multiple intakes located within a specific waterbody or along a coastal segment are difficult to quantify and are not typically assessed. Thus, EPA is concerned that this type of cumulative impact is largely unknown and has not adequately been accounted for in evaluating impacts.

A total of 408,000 million gallons of water per day were withdrawn from waters of the United States in 2000 for cooling, irrigation, manufacturing processes, drinking, livestock watering and other purposes,[31] of which cooling water intake from Phase III facilities constitutes 23,000 million gallons of water per day, or approximately 6% of total water withdrawal. Additional stresses on aquatic systems include, but are not limited to, nutrient, toxics, and sediment loadings; low dissolved oxygen; habitat loss; and stormwater runoff. Although EPA recognizes that a nexus between a particular stressor and adverse environmental impact may be difficult to establish with certainty, EPA believes stressors that cause or contribute to the loss of aquatic organisms and habitat, such as those described above, may incrementally impact the health and long-term viability of aquatic resources. EPA analyses suggest that over 99 percent of all existing facilities with cooling water withdrawals that EPA surveyed in its section 316(b) survey of existing facilities are located within two miles of waters that are identified as impaired by a State or Tribe (*see* 66 FR 65256, 65297). Thus, the Agency is concerned that to the extent that many of the aquatic organisms subject to the effects of cooling water withdrawals reside in impaired waterbodies, they are potentially more vulnerable to cumulative impacts from an array of physical and chemical anthropogenic stressors.

Finally, EPA believes that an aquatic population's potential compensatory ability—the capacity for a species to increase its survival, growth, or reproduction in response to reductions sustained to its overall population size—may be compromised by impingement and entrainment losses in

[28] Tondreau, R., J. Hey and E. Shane, Morningside College. 1982. Missouri River Aquatic Ecology Studies: Ten Year Summary (1972—1982). Prepared for Iowa Public Service Company, Sioux City, Iowa.

[29] Schmitt, R.J. and C.W. Osenberg. 1996. Detecting Ecological Impacts. Academic Press, San Diego, CA.

[30] EPRI 1999. Catalog of Assessment Methods for Evaluating the Effects of Power Plant Operations on Aquatic Communities. TR–112013, EPRI, Palo Alto, CA.

[31] Hutson, S.S., N.L. Barber, J.F. Kenny, K.S. Linsey, D.S. Lumia, and M.A. Maupin. 2004. Estimated Use of Water in the United States in 2000. U.S. Geological Survey Circular 1268.

conjunction with all the other stressors encountered within a population's natural range, as well as impingement and entrainment losses occurring consistently over extended periods of time. As discussed in the Phase I new facility rule (*see* 66 FR 65294), EPA is concerned that even if there is uncertainty about the extent to which cooling water intake structures alone reduce a population's compensatory reserve, this stressor, in combination with the multitude of other stressors acting upon a species, can potentially adversely affect population sustainability.[32] Moreover, EPA notes that the opposite effect or ''depensation'' (decreases in recruitment as stock size declines)[33] may occur if a population's size is reduced beyond a critical threshold. Depensation can lead to further decreases in population abundances that are already seriously depleted and, in some cases, recovery of the population may not be possible even if the stressors are removed.[34] [35] [36]

In conclusion, EPA believes that there are multiple types of undesirable and unacceptable environmental impacts that may be associated with Phase III facilities, depending on conditions at the individual site. EPA solicits comment and additional data characterizing the type and extent of these impacts.

VI. Basis for the Proposed Requirements

A. What Is the Best Technology Available for Minimizing Adverse Environmental Impact at Phase III Existing Facilities?

Under today's proposed rule, existing Phase III facilities would be subject to the same national performance standards as Phase II existing facilities, and would be authorized to meet these requirements through the same five compliance alternatives provided in the Phase II rule. EPA is proposing to codify Phase III requirements in 40 CFR 125, subpart K. See section II for a discussion of the three co-proposed thresholds that in part determine which facilities would constitute a Phase III existing facility. Requirements for facilities that have, or are required to have, an NPDES permit and withdraw cooling water from waters of the United States, but do not meet the applicable flow threshold of today's proposed rule, or use less than 25 percent of the water withdrawn exclusively for cooling purposes, would continue to be established by permit writers on a case-by-case, best professional judgment basis. Today's proposed rule also would establish requirements for new offshore oil and gas extraction facilities. See section VI.A.5 for a discussion of proposed requirements for new offshore oil and gas extraction facilities. As with EPA's Phase I and II rules, States and authorized Tribes retain the authority to impose additional requirements as authorized by their laws and regulations.

EPA is proposing national performance standards for the reduction of impingement mortality and, when appropriate, entrainment. EPA developed these proposed performance standards in part based on a variety of technologies, but the proposed rule would not mandate the use of any specific technology. Rather, the proposed performance standards consist of ranges of reductions in impingement mortality and/or entrainment (*e.g.*, reduce impingement mortality by 80 to 95 percent and/or entrainment by 60 to 90 percent) based on the effectiveness of commercially available, economically practicable technologies operating in a range of aquatic environments. These proposed performance standards reflect the best technology available for minimizing adverse environmental impact determined on a national categorical basis. The type of performance standard applicable to a particular facility (*i.e.*, reductions in impingement mortality only or reductions in both impingement mortality and entrainment) would vary by the source waterbody type (*i.e.*, freshwater river/stream, estuary/tidal river, ocean, Great Lake, or lake/reservoir) and the proportion of the waterbody withdrawn.

Under this proposal, a Phase III existing facility could select among the same compliance alternatives available under the Phase II rule: (1) Demonstrate that it has reduced or will reduce its cooling water intake flow commensurate with a closed-cycle recirculating system, or that it has reduced, or will reduce, the maximum through-screen design intake velocity to 0.5 feet per second or less (the through-screen design intake velocity criteria meets the performance standards to reduce impingement mortality only; the facility may still be subject to performance standards for entrainment); (2) demonstrate that its existing design and construction technologies, operational measures, and/or restoration measures meet the applicable performance standards and restoration requirements; (3) demonstrate that it has selected design and construction technologies, operational measures, and/or restoration measures that will, in combination with any existing design and construction technologies, operational measures, and/or restoration measures, meet the applicable performance standards and restoration requirements; (4) demonstrate that it will install or has installed and properly operates and maintains an approved design and construction technology; or (5) demonstrate that it has selected, installed, and is properly operating and maintaining, or will install and properly operate and maintain, design and construction technologies, operational measures, and/or restoration measures that the Director has determined to be the best technology available for the facility based on application of a specified cost-to-cost test or a cost-to-benefit test.

EPA is proposing this regulatory scheme based on its assessment that Phase III existing facilities (existing facilities not covered under the Phase II rule with a design intake flow that meets or exceeds one of the co-proposed thresholds) and Phase II facilities (existing power producers with a design intake flow of 50 MGD or greater) can employ similar technologies to minimize adverse environmental impacts, specifically impingement mortality and entrainment. EPA found no significant differences in either the types of cooling water intake structures or types of fish protection technologies used by proposed Phase III existing facilities and Phase II facilities. Moreover, EPA found that these technologies are economically practicable at the Phase III existing facilities proposed for coverage under the three proposed options.

Existing facilities that do not meet one of the co-proposed design intake flow thresholds (but meet the other applicability criteria) would continue to be subject to requirements established by permit writers on a case-by-case, best

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[32] Hutchings, J.A. and R.A. Myers. 1994. What can be learned from the collapse of a renewable resource? Atlantic cod, Gadus morhus, of New Foundland and Labrador. Canadian Journal of Fisheries and Aquatic Sciences 51:2126–2146.

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[35] Hutchings, J.A. and R.A. Myers. 1994. What can be learned from the collapse of a renewable resource? Atlantic cod, Gadus morhus, of New Foundland and Labrador. Canadian Journal of Fisheries and Aquatic Sciences 51:2126–2146.

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professional judgment basis, rather than to national categorical standards.

EPA notes that under its current regulations at 125.90(b), any existing facility that is a point source, that uses or proposes to use cooling water intake structures to withdraw cooling water from waters of the United States, and that is not subject to Subpart J or any other section 316(b)-related subpart in Part 125 must meet the requirements of CWA section 316(b) as determined by the Director on a case-by-case, best professional judgment (BPJ) basis. In today's Notice, EPA is proposing national categorical requirements for some of the facilities that, under § 125.90(b), would otherwise be subject to section 316(b) requirements established on a BPJ basis. Those facilities outside the scope of today's proposed rule would continue to be regulated on a case by case, BPJ basis, under Part 125 pursuant to § 125.90(b). After considering public comment on today's proposed regulation and any additional information developed as part of this rulemaking, EPA may decide to continue to rely on § 125.90(b) for all existing facilities not subject to Subpart J or any other section 316(b)-related subpart in Part 125 in lieu of today's proposed national categorical requirements.

1. Basis for Proposed Performance Standards

Under today's proposal, Phase III existing facilities would be subject to the same performance standards promulgated in the final Phase II cooling water intake structure rule (§ 125.103(b)). The basis for these performance standards is discussed in detail in the preamble to the final Phase II rule (69 FR 41576, July 9, 2004).

Under two of the three options proposed today, Phase III existing facilities are subject either to performance standards to reduce impingement mortality only, or performance standards to reduce both impingement mortality and entrainment. EPA believes that impingement mortality and entrainment are appropriate metrics for performance because these are primary and distinct types of harmful impacts associated with the use of cooling water intake structures.

All Phase III existing facilities demonstrating compliance under alternatives two, three, and four described above (proposed § 125.103(a)(2), (3), and (4)) would be subject to performance standards for impingement mortality. The impingement mortality performance standard would require a Phase III existing facility that complies under § 125.103(a)(2), (3), and (4)) to reduce impingement mortality for all life stages of fish and shellfish by 80 to 95 percent from the calculation baseline. The impingement mortality and entrainment performance standards under § 125.103(b) would also be used for determining eligibility and site-specific requirements for facilities choosing to comply under compliance alternative five (see proposed § 125.103(b)).

Both impingement mortality and entrainment performance standards would apply to Phase III existing facilities that withdraw cooling water from a tidal river, estuary, ocean, or one of the Great Lakes. Under the proposed options that would establish a design intake flow threshold at 50 MGD or higher or 200 MGD or higher, both standards would also apply to facilities that use cooling water from a freshwater river or stream and have a design intake flow greater than five percent of the mean annual flow. EPA is proposing to apply both standards because these facilities have the potential to cause more significant entrainment impacts. The entrainment standard, where applicable, would require a Phase III existing facility to reduce entrainment of all life stages of fish and shellfish by 60 to 90 percent from the calculation baseline. Performance standards for entrainment would not apply to Phase III existing facilities with design intake flows of five percent or less of the mean annual flow of a freshwater river or stream, and those that withdraw cooling water from a reservoir or lake (other than one of the Great Lakes). EPA believes such facilities have a lower propensity for causing significant entrainment impacts due to lower proportional intake flow or general waterbody characteristics.

Although facilities that withdraw from lakes (other than the Great Lakes) and reservoirs would not be subject to entrainment performance standards, they would be subject to other specific performance standards under the 50 MGD or higher proposed option, or 200 MGD or higher proposed option. If such a facility proposes to increase the design intake flow of the cooling water intake structure, the increase in total design intake flow must not disrupt the natural thermal stratification or turnover pattern of the source water except in cases where the disruption does not adversely affect the management of fisheries (see proposed § 125.103(b)(3)).

The performance standards applicable to Phase III existing facilities are not based on a single technology but, rather, are based on consideration of a range of technologies that EPA has determined to be commercially available for the Phase III industries affected as a whole and to have acceptable non-water quality environmental impacts. Because the proposed requirements implementing section 316(b) would be applied in a variety of settings and to Phase III existing facilities of different types and sizes, no single technology is most effective at all such facilities. A range of available technologies has therefore been used as the basis for the performance standards.

EPA developed the performance standards for impingement mortality reduction based on an analysis of the efficacy of the following technologies: (1) Fine and wide-mesh wedgewire screens, as well as aquatic filter barrier systems, that can reduce mortality from impingement by up to 99 percent or greater compared with conventional once-through systems; (2) barrier nets that may achieve reductions of 80 to 90 percent; and (3) modified screens and fish return systems, fish diversion systems, and fine mesh traveling screens and fish return systems that have achieved reductions in impingement mortality ranging from 60 to 90 percent as compared to conventional once-through systems with no impingement mortality controls. Data available to EPA indicate that these technologies can be used to achieve the reductions in impingement mortality and/or entrainment specified in the performance standards. EPA estimates that 35 percent of potential Phase III existing facilities (*i.e.* with an intake greater than 2 MGD) currently use passive intake technology (e.g., wedgewire screens, etc.), 12 percent use fine mesh screens, 6 percent use fish diversion technologies, and 5 percent use fish handling technologies. Available performance data for entrainment reduction are not as comprehensive as impingement data. However, aquatic filter barrier systems, fine mesh wedgewire screens, and fine mesh traveling screens with fish return systems have been shown to achieve 80 to 90 percent or greater reduction in entrainment compared with conventional once-through systems without entrainment controls. EPA notes that screening to prevent organism entrainment may cause impingement of those organisms instead.

The performance standards proposed at § 125.103(b) are based on the type of waterbody in which the intake structure is located, the volume of water withdrawn by a facility, and the facility capacity utilization rate. Under the final Phase II rule, EPA grouped waterbodies into five categories: (1) Freshwater rivers or streams, (2) lakes or reservoirs,

(3) Great Lakes, (4) tidal rivers and estuaries, and (5) oceans. This proposal would apply these same categories to Phase III existing facilities. The Agency considers location, one aspect of which is waterbody type, to be an important factor in addressing adverse environmental impact caused by cooling water intake structures. Because different waterbody types have the potential for different adverse environmental impacts, the requirements to minimize adverse environmental impact would vary by waterbody type.

The performance standards for Phase III existing facilities with cooling water intake structures located in a tidal river or estuary are a reduction of impingement mortality by 80 to 95 percent and entrainment by 60 to 90 percent for fish and shellfish. Data available to EPA indicate that estuaries and tidal rivers are among the more susceptible waterbodies to adverse impacts from impingement mortality and entrainment. The reproductive strategies of tidal river and estuarine species, together with other physical and biological characteristics of those waters, make them more susceptible to impacts from cooling water intake structures (66 FR 28857–28859; 68 FR 17140). In contrast, many aquatic organisms found in non-tidal freshwater rivers and streams are less susceptible to entrainment due to their demersal (bottom-dwelling) nature and the fact that they do not typically have planktonic (free-floating) egg and larval stages (66 FR 28857; 68 FR 17140).

Absent entrainment control technologies, entrainment at a particular site is generally proportional to intake flow at that site. EPA believes it is reasonable to vary performance standards by the potential for adverse environmental impact associated with flow levels and a waterbody type. Under two of the three proposed options, EPA would limit the requirement for entrainment controls in fresh waters to those facilities that withdraw the largest proportion of water from freshwater rivers or streams because they have a greater potential to impinge and entrain larger numbers of fish and shellfish. EPA is not requiring entrainment reductions in freshwater rivers or streams where facilities withdraw 5 percent or less of the source water annual mean flow because such facilities generally have a lower propensity for causing significant entrainment impacts due to the lower proportion of intake flow in combination with the characteristics of the waterbody.

This proposed rule would also establish a specific performance standard for lakes (other than a Great Lake) or reservoirs, in order to protect the thermal stratification of the waterbody. The natural thermal stratification or turnover pattern of a lake is a key characteristic that is potentially affected by the intake flow (which can alter temperature and/or mixing of cold and warm water layers) and location of cooling water intake structures within such waterbodies. The Great Lakes are subject to more stringent standards than other lakes or reservoirs, and must meet performance standards for reduction in both impingement mortality and entrainment. As described in the Phase I proposed rule (65 FR 49086) and Notice of Data Availability (NODA) (66 FR 28858), and the Phase II final rule (69 FR 41576), EPA believes that the Great Lakes have areas of high productivity and sensitive critical habitats that would require a greater level of protection.

The performance standards for Phase III existing facilities with cooling water intake structures located in an ocean are a reduction of impingement mortality by 80 to 95 percent and entrainment by 60 to 90 percent for fish and shellfish. EPA is establishing requirements for facilities withdrawing from oceans that are similar to those for tidal rivers and estuaries because the coastal zone of oceans (where coastal cooling water intake structures withdraw water from) are highly productive areas for fish and shellfish. (See the Phase I proposed rule (65 FR 45060) and documents in the record for the Phase I new facility rule (Docket W–00–03) such as 2–013A through O, 2–019A–R11, 2–019A–R12, 2–019A–R33, 2–019A–R44, 2–020A, 3–0059. EPA is also concerned about the extent to which fishery stocks that rely upon tidal rivers, estuaries and oceans for habitat are over utilized and seeks to minimize the impact that cooling water intake structures may have on these species or forage species on which these fishery stocks may depend. See 69 FR 41600.

As in the Phase I and Phase II rules, EPA would apply performance standards for minimizing adverse environmental impact based on a relatively easy to measure and certain metric-reduction of impingement mortality and entrainment. Although adverse environmental impact associated with cooling water intake structures can extend beyond impingement mortality and entrainment, EPA is proposing this approach because impingement mortality and entrainment are primary, harmful environmental effects that can be reduced through the use of specific technologies. In addition, those impacts that exist at the population, community, and ecosystem levels will also be reduced by reducing impingement mortality and entrainment. Using impingement mortality and entrainment as metrics provide certainty about performance standards and streamlines and thus speeds the issuance of permits.

The performance standards are expressed in the form of ranges rather than a single performance benchmark because of the uncertainty inherent in predicting the efficacy of any one of these technologies, or a combination of these technologies, across the spectrum of facilities operating in a range of aquatic environments subject to today's proposed rule. See 69 FR 41600. In specifying a range, EPA anticipates that facilities will select the most cost-effective technologies or operational measures to achieve the performance level (within the stated range) based on conditions found at their site, and that Directors will review the facilities' applications to ensure that appropriate alternatives were considered. Proper selection, operation, and maintenance of these technologies would serve to increase potential efficiencies of the technologies. EPA also expects that some facilities may be able to meet these performance requirements by selecting and implementing a suite (i.e., more than one) of technologies and operational measures and/or, as discussed in this section, by undertaking restoration measures.

Several additional factors support EPA's expectation that the impingement mortality and entrainment reduction reflected in the performance standards can eventually be achieved by all facilities using the design and construction technologies on which the standards were based. First, a significant amount of the data available to EPA (e.g., section 316(b) permitting studies) were developed during early section 316(b) permitting and do not reflect recent developments or experience using these technologies. Second, many conventional barrier and return system technologies have not been optimized as would be encouraged by this rule. Finally, some facilities could achieve further reductions (estimated at 15–30 percent) in impingement mortality and entrainment by providing for seasonal flow restrictions, variable speed pumps, and other operational measures and innovative flow reduction alternatives that can achieve greater reductions.

The calculation baseline used to determine compliance with performance standards is defined in proposed § 125.102 as an estimate of

impingement mortality and entrainment that would occur at a site assuming: (1) The cooling water system had been designed as a once-through system; (2) the opening of the cooling water intake structure is located at, and the face of the standard 3/8 inch mesh traveling screen is oriented parallel to, the shoreline near the surface of the source waterbody; and (3) the baseline practices and procedures are those that the facility would maintain in the absence of any operational controls, including flow or velocity reductions, implemented in whole or in part for the purposes of reducing impingement mortality and entrainment. Alternatively, the facility could choose to use the current level of impingement mortality and entrainment as the calculation baseline. The calculation baseline could be estimated using: historical impingement mortality and entrainment data from the facility or from another facility with comparable design, operational, and environmental conditions; current biological data collected in the waterbody in the vicinity of the facility's cooling water intake structure; or current impingement mortality and entrainment data collected at the facility. Further, a facility could request that the calculation baseline be modified to be based on a location of the opening of the cooling water intake structure at a depth other than at or near the surface if it can demonstrate to the Director that the other depth would correspond to a higher baseline level of impingement mortality and/or entrainment. EPA is proposing to use this definition because it represents the most common default conditions the Agency could identify to give facilities credit for design and construction technologies, operational measures, and/or restoration measures that they have already implemented to minimize adverse environmental impact, while providing a clear and relatively simple definition. In many cases, existing technologies at the site show some reductions in impingement mortality and entrainment when compared to this baseline. In such cases, impingement mortality and entrainment reductions (relative to the calculated baseline) achieved by these existing technologies should be counted toward compliance with the performance standards. In addition, operational measures such as operation of traveling screens that exceed the baseline (*e.g.*, screens finer than 3/8 inch mesh, or with fish handling capacity), employment of more efficient return systems, and even location choices should be credited for any corresponding reduction in impingement mortality and entrainment. See section VII of this preamble for a discussion of how the calculation baseline is used to compare facility performance with the proposed rule's performance standards.

In the Phase II final regulations (*see* 69 FR 41578), EPA considered the rate of use of the electric power generation facility in setting performance requirements. Under the Phase II rule, power producing facilities with a capacity utilization rate of less than 15 percent are only required to meet the impingement mortality reduction requirements, based on EPA's determination that entrainment impacts below this threshold would be minimal. Today's proposed rule does not contain an analogous provision for manufacturing facilities, as EPA has been unable to identify a similar threshold of operations below which impacts would be considered minimal. EPA requests comment on the availability of such a threshold that would result in lesser requirements for facilities that do not operate full time, thus minimizing burdens to these facilities while still protecting the source waterbody.

2. Basis for Five Proposed Compliance Alternatives

Today's proposed rule would authorize a Phase III existing facility with a total design intake flow that exceeds the specified threshold to choose one of five alternatives for establishing the best technology available for minimizing adverse environmental impact at the facility. These compliance alternatives (proposed § 125.103(a)) would be consistent with those promulgated in the final Phase II rule (40 CFR 125.94(a)). Each proposed alternative is described below.

This proposed approach provides a high degree of flexibility for Phase III existing facilities to select the most effective and efficient approach and technologies for minimizing adverse environmental impact associated with their cooling water intake structures. This proposed approach also reflects EPA's judgment that, given the wide range of various factors that affect the environmental impact posed by Phase III existing facilities, different technologies or different combinations of technologies can be used and optimized to achieve the performance standards. EPA requests comment on all aspects of this proposed approach.

a. Meeting Performance Standards Through Reducing Intake Flow Commensurate With a Closed Cycle Recirculating System or Reduced Design Intake Velocity

EPA is proposing that a Phase III existing facility could meet applicable performance standards through complying with § 125.103(a)(1)(i) or (ii). Under proposed § 125.103(a)(1)(i), any Phase III existing facility that reduces its flow to a level commensurate with a closed-cycle, recirculating cooling system would be deemed to satisfy the applicable impingement mortality and entrainment performance standards for all waterbodies under § 125.103(b). Such facilities may still be subject to requirements under § 125.103(e). Facilities that select this compliance alternative either through the use of existing closed-cycle recirculating system technology at the plant, or by retrofitting their facility, would not be required to further demonstrate that they meet the applicable performance standards.

Available data described in Chapter 3 of the Phase II Existing Facility Technical Development Document (DCN 7–0004) suggest that closed-cycle, recirculating cooling systems (*e.g.*, cooling towers or ponds) can reduce mortality from impingement by up to 98 percent and entrainment by up to 98 percent when compared with conventional once-through systems.[37] Although closed-cycle, recirculating cooling is not one of the technologies on which the performance standards are based, use of a closed-cycle, recirculating cooling system would achieve the performance standards, and therefore, facilities that reduce their flow commensurate with closed-cycle, recirculating cooling systems would be deemed to have met the performance standards for both impingement mortality and entrainment. Under this proposal, § 125.103(a)(1)(i) would thus constitute a compliance alternative for

[37] Reducing the cooling water intake structure's capacity is one of the most effective means of reducing entrainment (and impingement mortality). For the traditional steam electric utility industry, facilities located in freshwater areas that have closed-cycle, recirculating cooling water systems can, depending on the quality of the make-up water, reduce water use by 96 to 98 percent from the amount they would use if they had once-through cooling water systems. Steam electric generating facilities that have closed-cycle, recirculating cooling systems using salt water can reduce water usage by 70 to 96 percent when make-up and blowdown flows are minimized. The lower range of water usage would be expected where State water quality standards limit chloride to a maximum increase of 10 percent over background and therefore require a 1.1 cycle of concentration. The higher range should be attainable where cycles of concentration up to 2.0 are used for the design.

Phase III existing facilities based on the use of a closed-cycle, recirculating cooling system. While EPA based the requirements of the Phase I new facility rule on the efficacy of closed-cycle recirculating systems (66 FR 65273—65274), EPA has determined that this technology is not economically practicable for some Phase III existing facilities. EPA is nonetheless aware that approximately 6 percent of Phase III manufacturers with a design intake flow of 50 MGD or greater, and 3 percent of Phase III manufacturers with a design intake flow of 200 MGD or greater, have installed this highly effective technology and should meet this streamlined alternative.

Similarly, under proposed § 125.103(a)(1)(ii), any Phase III existing facility that reduces its design intake velocity to 0.5 feet per second or less would be deemed to have met the performance standards for impingement mortality and would not be required to demonstrate further that it meets the performance standards for impingement mortality. However, if the facility is subject to performance standards for entrainment, it would need to otherwise demonstrate compliance with entrainment performance standards.

As EPA discussed in the Phase II proposed rule at 67 FR 17151 and Phase I final rule at 66 FR 65274, intake velocity is one of the key factors that can affect the impingement of fish and other aquatic biota, since in the immediate area of the intake it exerts a direct physical force against which fish and other organisms must act to avoid impingement and entrainment. As discussed in those notices, EPA compiled data from three swim speed studies (University of Washington study, Turnpenny, and EPRI) (DCN 2–28A–C) and these data indicated that a 0.5 feet per second velocity would protect at least 96 percent of the tested fish. As further discussed, EPA also identified Federal documents (Boreman, DCN 1–5003–PR; Bell (1990); National Marine Fisheries Service (NMFS), (1997); an early swim speed and endurance study performed by Sonnichsen *et al.* (1973); and fish screen velocity criteria that support this approach (DCN 2–29).

b. Meeting Performance Standards Through the Use of Design and Construction Technologies, Operational Measures, and/or Restoration Measures

Under the second and third proposed Phase III compliance alternatives, a facility could either demonstrate to the Director that the facility's existing design and construction technologies, operational measures, and/or restoration measures already meet the minimum performance standards specified under § 125.103(b) and (c), or that it has selected design and construction technologies, operational measures, and/or restoration measures or some combination thereof that will meet these performance standards (*see* proposed § 125.103(a)(2) and (3)).

Available data indicate that barrier and/or fish handling technologies are available on a national basis for use by Phase III existing facilities.[38] These technologies exist and are in use at various Phase III existing facilities and, thus, EPA considers them collectively technologically available. Many Phase III existing facilities that do not already have closed-cycle cooling systems have these or other technologies in place that reduce impingement mortality or entrainment to levels that would meet the proposed rule requirements (*e.g.*, EPA estimates this is the case for 23 percent of manufacturers with a design intake flow of 50 MGD or greater, see the TDD for more details). The fact that these technologies are collectively utilized means that, in general, one or more technologies within the suite would be available to each Phase III existing facility to meet the applicable performance standards. (If this is not the case for a specific facility, it can utilize compliance alternative five below.)

EPA believes that the design and construction technologies necessary to meet the requirements are commercially available and economically practicable for existing facilities, because facilities can and have installed many of these technologies years after a facility began operation. Typically, additional design and construction technologies such as fine mesh screens, wedgewire screens, fish handling and return systems, and aquatic filter fabric barrier systems can be installed during a scheduled outage (operational shutdown).

In addition, EPA's survey data shows that the types of intakes, technologies currently employed, or technologies that may be retrofitted at proposed Phase III existing facilities are no different than those at Phase II facilities. For example, EPA identified one Phase III facility that retrofitted ten 36-inch wedgewire T-screens. Another retrofit example is an electric generator that is below the Phase II threshold that replaced its perforated plate with wedgewire T-screens. Examples of Phase II facilities that installed these technologies after they initially started operating may be found at 69 FR 641602.

c. Meeting Performance Standards Through Use of a Pre-Approved Design and Construction Technology

Under the fourth compliance alternative in today's proposed regulation, a Phase III existing facility would be able to demonstrate that it meets specified conditions and has installed and properly operates and maintains a pre-approved technology (*see* proposed § 125.103(a)(4)). EPA has identified one pre-approved technology: Submerged cylindrical wedgewire screen technology to treat the total cooling water intake flow. This pre-approved technology was identified in the Phase II rule, and is proposed as a compliance option for Phase III existing facilities (*see* proposed § 125.108). There are five conditions that would need to be met in order to use this technology to comply with the proposed rule: (1) The cooling water intake structure is located in a freshwater river or stream; (2) the cooling water intake structure is situated such that sufficient ambient counter currents exist to promote cleaning of the screen face; (3) the through screen design intake velocity is 0.5 feet per second or less; (4) the slot size is appropriate for the size of eggs, larvae, and juveniles of any fish and shellfish to be protected at the site; and (5) the entire main cooling water flow is directed through the technology (small flows totaling less than two MGD for auxiliary plant cooling uses are excluded). Under this proposal, Directors would be explicitly authorized under § 125.108 to pre-approve other technologies for use at facilities with other specified characteristics within their respective jurisdiction after providing the public with notice and an opportunity to comment on the request for approval of the technology. The Director's authority to pre-approve other technologies would not be limited to technologies for use by facilities located on freshwater rivers and streams.

EPA has proposed this compliance alternative in response to Phase II proposed rule comments and Phase III small entity comments (provided pursuant to consultations mandated by the Small Business Regulatory Enforcement Fairness Act) that suggested that EPA provide an additional, more streamlined compliance option that would allow a facility to implement certain specified technologies that are deemed highly protective in exchange for reducing the implementation burden, including reducing the scope of the

[38] As previously noted, as an example of technologies in use EPA estimates that 35 percent of Phase III existing facilities currently use passive intake technology (*e.g.*, wedgewire screens, *etc.*), 12 percent use fine mesh screens, 6 percent use fish diversion technologies, and 5 percent use fish handling technologies.

Comprehensive Demonstration Study. (*See,* 68 FR 13522, 13539; March 19, 2003 and DCN 7–0006). EPA evaluated the effectiveness of specific technologies using the impingement mortality and entrainment reduction performance standards as assessment criteria. The approved cylindrical wedgewire screen technology has a demonstrated ability to reduce impingement mortality by 80 to 95 percent for fish and shellfish and, if required, reduce entrainment by 60 to 90 percent for any stages of fish and shellfish at facilities that meet the conditions specified in proposed § 125.108(a)(1). Thus, the technology has a demonstrated ability to meet the most stringent performance standards that would apply to any facility situated on a freshwater river or stream. (*See* DCN 1–3075, 1–5069, 1–5070, 3–0002, and 4–4002B. Also, *see* DCN 6–5000 and Chapter 3 of the Phase II Technical Development Document (DCN 6–0004)). Because cylindrical wedgewire screens are believed to be effective when deployed under the specified conditions and properly maintained, facilities that select this compliance option are provided substantially streamlined requirements for completing the Comprehensive Demonstration Study. However, facilities that select this option would still be required to prepare a Technology Installation and Operation Plan and a Verification Monitoring Plan to monitor the effectiveness of the technology at their sites in meeting the performance standards.

Referenced below are examples of Phase III facilities that installed this technology after they initially started operating.

Sherburne County Generating Plant. A Phase III electric generator, Sherburne County is located on the upper Mississippi River in Minnesota. The facility began operations in 1976 and operates one cooling water intake structure. The facility also uses a closed-cycle, recirculating cooling system. In 1986, Sherburne County replaced its existing intake technology (a perforated plate) with cylindrical wedgewire screens.

Tosco Refinery. Oil refineries are one of the industry sectors examined in the Phase III rule. Located in Rodeo, California, the Tosco Refinery replaced its traveling screens with cylindrical wedgewire screens in 2000.

To date, EPA has not identified new data or information that could be used to establish other technologies as pre-approved on a nationwide basis. Several stakeholders suggested EPA continue to evaluate whether other technologies could qualify as pre-approved technologies. EPA solicits comment and new data, including appropriate site conditions, on other candidate technologies for pre-approval.

d. Site-Specific Determination of Best Technology Available To Minimize Adverse Environmental Impact

Under this proposed compliance alternative, a Phase III existing facility also could comply with the proposed rule by seeking a site-specific determination of the best technology available to minimize adverse environmental impact by demonstrating to the Director that its cost of complying with the applicable performance standards would be significantly greater than the costs considered by EPA for a like facility when establishing such performance standards, or that its costs would be significantly greater than the benefits of complying with such performance standards at the facility. (*See* proposed § 125.103(a)(5)(i) and (ii)). If a facility satisfies one of the two proposed cost tests in § 125.103(a)(5), then the Director would have to establish site-specific alternative requirements based on design and construction technologies, operational measures, and/or restoration measures that achieve an efficacy that is, in the judgment of the Director, as close as practicable to the applicable performance standards without resulting in costs that are significantly greater than either the costs considered by the Administrator in establishing the applicable performance standards, or the benefits at the facility.

As discussed in the Phase II rule, in developing the proposed standards in § 125.103(b) and the proposed compliance alternatives in § 125.103(a)(2)–(4), EPA considered several factors, including efficacy, availability, ease of implementation, indirect effects, the costs that EPA expects all existing facilities to incur (national costs) and the benefits if all existing facilities meet the performance standards (national benefits). These proposed site-specific compliance options would give Phase III existing facilities flexibility to demonstrate that the best technology available to minimize adverse environmental impact at their particular sites may be less stringent than would otherwise be required if the facility selected one of the compliance alternatives in § 125.103(a)(2), (3) or (4).

i. Basis of the Cost-Cost Test

For a number of related reasons discussed below, EPA chose to use a comparison of a facility's actual costs to the costs EPA estimated that a like facility would incur to meet the national performance standards (a ''cost-cost test'') as a basis for obtaining a site-specific determination of best technology available to minimize adverse environmental impact. EPA's record for this proposed rule shows that for Phase III existing facilities withdrawing greater than the three co-proposed thresholds, the requirements in today's proposed rule would be technically available and generally economically practicable. However, EPA recognizes that it may not have anticipated all site-specific costs that a facility would incur, or that the costs for retrofitting may significantly exceed those EPA considered. For example, detailed information on some factors important to the effectiveness and costs of the technologies, such as debris loading and the presence of navigational channels within the waterbody at which cooling water intakes are sited, were not available. Moreover, the information EPA used to develop its costs was in some cases limited by the fact that, while EPA sent surveys to all known electric generators and a sample of manufacturing facilities covered under today's proposed rule, only 42 percent of the total potential Phase II and Phase III universes were sent detailed questionnaires. The remaining 58 percent only received a short technical questionnaire which requested minimal characterization information. Also, EPA may not have elicited information regarding characteristics of a particular facility that, if known, would have either significantly changed EPA's cost estimates or demonstrated that none of the technologies on which the categorical requirements are based are economically achievable by the facility. Similarly, existing facilities have less flexibility than new facilities in selecting the location of their intakes and technologies for minimizing adverse environmental impact, and therefore it may be difficult for some facilities to avoid costs much higher than those EPA considered when establishing the performance standards. The cost-cost site-specific alternative ensures that the overall rule remains economically practicable for all facilities that would be subject to today's proposed rule. Despite EPA's best effort, site-specific costs are difficult to estimate in a national rule. For all of these reasons, EPA believes that the cost-cost site-specific compliance alternative is necessary to ensure that the proposed rule would be economically practicable for all Phase III existing facilities. In order to ensure that this alternative provides only the

minimum relaxation of performance standards that is needed to make the proposed rule economically practicable, proposed § 125.103(a)(5)(i) requires that the site-specific requirements achieve an efficacy that is as close as practicable to the applicable performance standards without resulting in costs that are significantly greater than those considered by the Administrator for a like facility when establishing the performance standards.

EPA is proposing at § 125.103(a)(5) to limit the comparison of like facilities to Phase III existing facilities within the scope of the rule. EPA believes this provision is necessary and appropriate because different cost assumptions were used in estimating costs for the Phase II and Phase III existing facilities. (These differences are discussed in detail in the relevant Technical Development Documents (DCN 6–0004 and DCN 7–0002.)

Legal Authority for the Cost-Cost Test

CWA section 316(b) authorizes a site-specific determination of best technology available. Although, CWA section 316(b) authorizes EPA to promulgate national categorical requirements, the variety of factors to be considered in determining these requirements—such as location and design—indicate that site-specific conditions can be highly relevant to the determination of best technology available to minimize adverse environmental impact. In addition to specifying best technology available in relation to a national categorical performance standard, today's proposed rule also authorizes a site-specific determination of best technology available when conditions at the site lead to a more costly array of controls than EPA had expected would be necessary to achieve the applicable performance standards.

This site-specific compliance option is similar to the ''fundamentally different factors'' provision in CWA section 301(n), which authorizes alternative requirements for sources subject to national technology-based standards for effluent discharges, if the facility can establish that it is fundamentally different with respect to factors considered by EPA in promulgating the national standard. The fundamentally different factors provision was added to the CWA in 1987, but prior to the amendment, both the Second Circuit and the Supreme Court upheld EPA's rules containing provisions for alternative requirements as reasonable interpretations of the statute. *NRDC* v. *EPA*, 537 F.2d 642, 647 (2d Cir. 1976) (''the establishment of the variance clause is a valid exercise of the EPA's rulemaking authority pursuant to section 501(a) which authorizes the Administrator to promulgate regulations which are necessary and proper to implement the Act''); *EPA* v. *National Crushed Stone Ass'n*, 449 U.S. 64 (1980) (approving EPA's alternative requirements provision in a standard adopted pursuant to CWA section 301(b)(1), even though the statute did not expressly permit a variance.) EPA's alternative site-specific compliance option in this proposed rule is similarly a reasonable interpretation of section 316(b) and a valid exercise of its rulemaking authority under CWA section 501.

Based on this interpretation, EPA and State permitting authorities have been implementing CWA section 316(b) on a case-by-case basis for over 25 years. Such a case-by-case determination of best technology available has been recognized by courts as being consistent with the statute. See *Hudson Riverkeeper Fund* v. *Orange and Rockland Util*, 835 F. Supp. 160, 165 (S.D.N.Y. 1993) (''This leaves to the permit writer an opportunity to impose conditions on a case by case basis, consistent with the statute'').

EPA reasonably interprets CWA section 316(b) to authorize it to consider costs of compliance in determining best technology ''available.'' (*See* section I.) Therefore, where EPA fails to consider a facility's unusual or disproportionate costs in setting the national requirements for best technology available, it reasonably authorizes permit authorities to set site-specific alternative limits to account for these costs. See *Riverkeeper* v. *EPA*, slip op. at 25 (2nd Cir. Feb. 3, 2004) (upholding site-specific alternative limits under the Phase I rule for new facilities where a particular facility faces disproportionate compliance costs).

ii. Basis of the Cost-Benefit Test

Under today's proposal, EPA would allow a facility to use a comparison of its costs to the benefits of meeting the performance standards at its site (a ''cost-benefit test'') as another basis for obtaining a site-specific determination of best technology available to minimize adverse environmental impact. Section 316(b) authorizes consideration of the environmental benefit to be gained by requiring that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for the purpose of minimizing adverse environmental impact. Accordingly, in proposing the technologies on which EPA based the compliance alternatives and performance standards as the best technologies available for existing facilities to minimize adverse environmental impact, EPA considered the national cost of those technologies in comparison to the national benefits—*i.e.*, the reduction in impingement mortality and entrainment that EPA estimated would occur nationally if all Phase III existing facilities withdrawing greater than any of the co-proposed thresholds selected one of the compliance options in § 125.103(a)(2) through (4). While EPA believes that there is considerable value in promulgating national performance standards under section 316(b) based on what EPA determines, on a national basis, to be the best technology available to minimize adverse environmental impact, EPA also recognizes that, at times, determining what is necessary to minimize adverse environmental impact can necessitate a site-specific inquiry. EPA's balance of the national costs and national benefits may not be similar to the comparison of costs and benefits at a specific site due to variations in: (1) The performance of intake technologies, and (2) characteristics of the waterbody in which the intake(s) are sited, including the resident aquatic biota. For example, there may be some facilities where the absolute numbers of fish and shellfish impinged and entrained is so minimal that the cost to achieve the required percentage reductions would be significantly greater than the benefits of achieving the required reductions at that particular site. More specifically, because of the characteristics of a particular waterbody, or the behavioral patterns of the fish or shellfish in that particular waterbody, there may be little or no impingement mortality or entrainment occurring at the site. For such a facility, the cost of reducing an already small amount of impingement mortality and entrainment by 80 to 95 percent and 60 to 90 percent, respectively, may be significantly greater than the benefits. In short, it may not be cost-effective and, therefore may be economically impracticable for a facility to achieve percentage reductions when attempting to save a small number of fish or shellfish. For example, in a waterbody that is already degraded, very few aquatic organisms may be subject to impingement or entrainment, and the costs of retrofitting an existing cooling water intake structure may be significantly greater than the benefits of doing so. By requiring best technology available to minimize adverse environmental impact, section 316(b) invites a consideration of both technology and environmental

conditions, including the potential for adverse impacts, in the receiving waterbody. EPA believes it is a reasonable interpretation of the statute to allow the Director to consider the results of meeting the performance standards in terms of reducing environmental impact (*i.e.*, the benefits) in cases where the costs of installing the technology are significantly greater than the reduction in environmental impacts would seem to warrant. As with the cost-cost site-specific provision, EPA also wants to ensure that any relaxation of the performance standards be the minimum necessary to ensure that the costs are not significantly greater than the benefits. Proposed § 125.103(a)(5)(ii) thus provides that alternative site-specific requirements must achieve an efficacy that is as close as practicable to the applicable performance standards without resulting in costs that are significantly greater than the benefits of meeting the performance standards at the facility.

Legal Authority for the Cost-Benefit Test

EPA believes that the Clean Water Act authorizes a site-specific determination of the best technology available to minimize adverse environmental impact where the costs of compliance with the rule's performance standards are significantly greater than its benefits. This authority stems from the statutory language of CWA section 316(b). Section 316(b) requires that cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. The object of the best technology available is explicitly articulated by reference to the receiving water: To minimize adverse environmental impact in the waters from which cooling water is withdrawn. In contrast, under section 301, the goal of BAT is explicitly articulated by reference to a different purpose, to make reasonable further progress toward the national goal of eliminating the discharge of all pollutants (section 301(b)(2)(A)). Similarly, under section 304, the goal of BPT and BCT is explicitly articulated by reference to the degree of effluent reduction attainable. (Section 304(b)(1)(A) and section 304(b)(4)(A))

EPA has previously considered the costs of technologies in relation to the benefits of minimizing adverse environmental impact in establishing section 316(b) limits, which historically have been done on a case-by-case basis. See, e.g., *In Re Public Service Co. of New Hampshire,* 10 ERC 1257 (June 17, 1977); *In Re Public Service Co. of New Hampshire,* 1 EAD 455 (Aug. 4, 1978); *Seacoast Anti-Pollution League* v. *Costle,* 597 F. 2d 306 (1st Cir. 1979). Under CWA section 316(b), EPA may consider the benefits that the technology-based standard would produce in a particular waterbody, to ensure that it will ''minimize adverse environmental impact.'' EPA believes that the technology-based standards established in this proposed rule will, as a national matter, ''minimize adverse environmental impact.'' However, the degree of minimization contemplated by the national performance standards may not be justified by site-specific conditions. In other words, depending on the circumstances of the receiving water, it may be that application of less stringent controls than those that would otherwise be required by the performance standards will achieve the statutory requirement to ''minimize'' adverse environmental impact, when considered in light of economic practicability. An extreme example is a highly degraded ship channel with few fish and shellfish, but such situations can only be identified and addressed through a site-specific assessment.

For these reasons, EPA reasonably interprets the phrase ''minimize adverse environmental impact'' in section 316(b) to authorize a site-specific consideration of the benefits of the technology-based standard on the receiving water. EPA continues to believe that any impingement or entrainment would be an adverse environmental impact, but has determined that section 316(b) does not require minimization of adverse environmental impact beyond that which can be achieved at a cost that is economically practicable. EPA believes that the relationship between costs and benefits is one component of economic practicability for purposes of section 316(b) and the legislative history indicates that economic practicability may be considered in determining what is best technology available for purposes of section 316(b). The legislative history of section 316(b) indicates that the term ''best technology available'' should be interpreted as ''best technology available commercially at an economically practicable cost.'' [39] EPA believes that allowing a relaxation of the performance standards when costs significantly exceed benefits, but only to the extent justified by the significantly greater costs, is a reasonable way of ensuring that adverse environmental impact be minimized at an economically practicable cost. This does not mean that there is a need to make a finding of ''adverse environmental impact'' before performance standards based CWA section 316(b) requirements would apply. Rather, EPA is authorizing an exception to national performance standards based requirements on a site-specific basis in limited circumstances: when the costs of complying with the national performance standards are significantly greater than the benefits of compliance at a particular site.

3. Why Is EPA Proposing National Requirements for New Offshore and Coastal Oil and Gas Extraction Facilities?

After EPA proposed the Phase I rule for new facilities (65 FR 49060, August 10, 2000), the Agency received adverse comment from operators of mobile offshore and coastal drilling units concerning the limited information about their cooling water intakes, associated impingement mortality and entrainment, costs of technologies, or achievability of the controls proposed by EPA. On May 25, 2001, EPA published a Notice of Data Availability (NODA) for Phase I that, in part, sought additional data and information about mobile offshore and coastal drilling units (*see* 66 FR 28857). In the Phase I final rule, EPA committed to ''propose and take final action on regulations for new offshore oil and gas extraction facilities, as defined at 40 CFR 435.10 and 40 CFR 435.40, in the Phase III section 316(b) rule.'' See 66 FR 65256. Today's proposed regulation would establish national requirements for new offshore oil and gas extraction facilities that use a cooling water intake structure to withdraw water from waters of the U.S.

Requirements for new offshore oil and gas extraction facilities are proposed in a new subpart N. New onshore oil and gas extraction facilities are already potentially covered under section 316(b) Phase I requirements; new offshore oil and gas extraction facilities that would be subject to subpart N include new coastal and offshore oil and gas extraction facilities. The proposed requirements for these facilities are similar to some, but not all, of the requirements contained in the Phase I rule applicable to other new facilities. For example, the Phase I requirement to reduce intake flow commensurate with a closed-cycle, recirculating cooling system would not apply to these facilities. EPA is seeking comment only on the new facility requirements contained in proposed Subpart N, which would be applicable to new offshore oil and gas extraction facilities.

Under today's proposed rule, new offshore oil and gas extraction facilities

[39] See 118 Cong. Rec 33,762 (1972), reprinted in 1 Legislative History of the Water Pollution Control Act Amendments of 1972, at 264 (1973)(Statement of Representative Don H. Clausen).

that withdraw greater than 2 MGD and that employ sea chests as cooling water intake structures, and are fixed facilities would have to comply with the requirements in § 125.134(b)(1)(ii). These requirements address intake flow velocity, specific impact concerns (e.g., threatened or endangered species, critical habitat, migratory or sport or commercial species), required information submission, monitoring, and recordkeeping. Under this proposal, new offshore oil and gas extraction facilities that withdraw greater than 2 MGD that do not employ sea chests as cooling water intake structures, and are fixed facilities would have to comply with the requirements in § 125.134(b)(1)(i). The one additional requirement for these facilities is § 125.134(b)(5), which requires the selection and implementation of design and construction technologies or operational measures to minimize entrainment of entrainable life stages of fish or shellfish. Fixed facilities can also choose to comply through Track II, which allows a site-specific demonstration that alternative requirements would produce comparable levels of impingement mortality and entrainment reduction. New offshore oil and gas facilities that are not fixed facilities would have to comply with the regulations at § 125.134(b)(1)(iii). Track II is not available to non-fixed (mobile) facilities because non-fixed facilities, which are expected to operate at multiple locations, would not be able to perform a site-specific demonstration. For this same reason, EPA has dropped some of the other site-dependent requirements for non-fixed facilities (*e.g.*, baseline biological assessment). EPA requests comment on the practicability of Track II demonstrations and other site-dependent requirements for non-fixed facilities.

EPA has limited information on environmental impacts associated with the use of cooling water intake structures at new offshore oil and gas extraction facilities but believes the potential for such impacts is sufficient to warrant including requirements for new offshore oil and gas extraction facilities in this proposed rule (*see* section V for more detailed discussion). In addition, although such technologies are not generally in use at existing offshore oil and gas extraction facilities, EPA believes that technologies are available for use by new facilities in this subcategory to meet the proposed requirements as described below. EPA requests comment, including data, on environmental impacts from, and availability of technologies for, cooling water intake structures at new offshore oil and gas extraction facilities.

Some offshore oil and gas extraction facilities employ an underwater compartment within the facility or vessel hull or pontoon through which sea water is drawn in or discharged, often called a ''sea chest.'' A passive screen (strainer) is often set along the flush line of the sea chest. Pumps draw seawater from open pipes in the sea chest cavity for a variety of purposes (*e.g.*, cooling water, fire water, and ballast water). These intakes are normally the only source of cooling water for the facility; therefore, it is crucial to the operation of these facilities that the intake structures be kept clean and clear of fish, jellyfish, plastic bags, and other debris. To accomplish this these intake structures can, and have been, designed for low intake velocity (*i.e.*, less than 0.5 feet per second) and/or include fish protection equipment; see the Technical Development Document for details.

As outlined in Alaska's oil and gas leasing requirements, oil and gas extraction facilities in Alaskan State waters are currently subject to an impingement control velocity limit of 0.1 feet per second (*i.e.*, more stringent than EPA's design requirement of 0.5 feet per second in the Phase I new facility rule to minimize impingement mortality of aquatic organism). These State regulations suggest that impingement controls that would meet the velocity requirements of this proposed rule are available for new offshore oil and gas extraction facilities in Alaskan or similar waters.

However, facilities using sea chests may have limited opportunities to meet the entrainment control requirements applicable to facilities subject to the Phase I rule. A 2003 literature survey by Mineral Management Services (DCN 7–0012) identified no evidence of entrainment controls successfully fitted to offshore oil and gas extraction vessels with sea chests such as drill ships, jack-ups, MODUs, and barges. EPA's data suggests that the only physical technology controls for entrainment at facilities with sea chests would entail installation of equipment projecting beyond the hull of the vessel. Such controls may not be feasible due to facility design requirements, even for new facilities that could avoid the challenges of retrofitting control technologies.

EPA does have limited information showing the entrainment reduction benefits of planar wedgewire screens. EPA is considering, and requests comment on, whether entrainment technologies, such as planar wedgewire screens, are available for use by facilities using sea chests and whether based on such technologies it would be appropriate to apply § 125.134(b)(5) (requiring design and construction technologies or operational measures to minimize entrainment of entrainable life stages of fish or shellfish) to such facilities.

EPA also considered whether all new offshore vessels could be constructed without employing sea chests. A technology must prove to be practicable to be a viable alternative to current technology. In this case, EPA treats a viable alternative to sea chests as any practical alternative configuration/technology successfully implemented at existing facilities, including those in other manufacturing industries, with similar seawater intake structures. EPA data suggests the only demonstrated design for drill ships and semi-submersible MODUs is to use sea chests because they allow the vessel to maintain appropriate fluid dynamics, overall optimal vessel shape, and a safe seaworthy profile. Therefore, EPA does not believe entrainment controls are feasible at such facilities.

For new offshore oil and gas extraction facilities with intake structures other than sea chests, EPA believes the proposed entrainment controls are feasible. For example, a caisson intake (as referred to here) is simply a steel pipe attached to a fixed structure that extends from an operating area down some distance into the water. It is used to provide a protective shroud around another process pipe or pump that is lowered into the caisson from the operating area. The most likely technologies to reduce impingement mortality and entrainment of marine life in this type of structure would be passive intake screens or velocity caps. Air sparges and copper nickel alloys can be used to control biofouling. Other technologies such as acoustic barriers, electro barriers or intake relocation may also be used.

In summary, EPA is proposing to apply requirements that are consistent with some—but not all—of the Phase I provisions to new offshore oil and gas extraction facilities, because of differences in technological availability between such facilities and those covered in the Phase I rule. Because available information indicates that it is not feasible for all new offshore oil and gas extraction facilities to employ closed-cycle recirculating cooling systems, new offshore oil and gas extraction facilities would not be subject to Phase I requirements based on closed-cycle recirculating cooling systems.

Specifically, new offshore oil and gas extraction facilities would not have to meet requirements equivalent to § 125.84(b)(1) (requiring that a facility reduce intake flow to a level commensurate with a closed-cycle recirculating cooling system) and § 125.84(d)(1) (Track II requirements using closed-cycle recirculating cooling systems as a baseline).

EPA is proposing to exclude new seafood processing vessels from the proposed national requirements. Data available to the Agency indicate that given the relatively low cooling water flows used by these vessels, the propensity for reduced intake of fish or debris due to the vessel's speed in relation to the intake's orientation and intake velocity, and their highly mobile character, these vessels are not likely to cause significant adverse environmental impacts. Further, data available to the Agency has not clearly identified available technologies that would reduce entrainment for such vessels. In addition, EPA is proposing to exclude new offshore liquified natural gas import terminals from the proposed national requirements. Such facilities withdraw water primarily for warming (not cooling) purposes, to heat liquified natural gas to temperatures at which it becomes a gas and can enter the natural gas distribution pipelines. Thus, it appears that these facilities would not meet the 25 percent exclusive cooling water use threshold, and would therefore be beyond the scope of section 316(b). Seafood processing vessels and new offshore liquified natural gas import terminals would continue to be subject to any requirements for their cooling water intake structures established by permit Directors on a case-by-case basis using best professional judgment.

EPA requests comment on all aspects of this proposed approach.

B. Economic Practicability

The legislative history of section 316(b) indicates that the term ''best technology available'' should be interpreted as ''best technology available commercially at an economically practicable cost.'' [40] This interpretation reflects congressional concern that the application of best technology available should not impose an impracticable and unbearable economic burden. Thus, EPA has conducted extensive analyses of the economic impacts of this proposed rule and the co-proposed options discussed above, using an integrated energy market model (the IPM) and an analysis of market costs and residential rates for the energy sector, and a discounted cash flow analysis model for the facility, firm, and market levels for manufacturers. For a complete discussion of these analyses, please refer to section VIII of this preamble or the Economic Analysis in support of this proposed rule (DCN 7–0002).

EPA believes that the requirements of this proposed rule reflect the best technology available at an economically practicable cost. EPA examined the effects of the proposed rule's compliance costs on capacity, generation, variable production costs, prices, net income, and other measures, both at the market and facility levels. In addition, the other economic analyses conducted by EPA showed that the costs for this proposed rule would be economically practicable.

EPA believes that a consideration of the relationship of costs to environmental benefits is an important component of economic practicability. As discussed in section VIII.C of the proposed Phase I rule (65 FR 49094), EPA has long recognized that there should be some reasonable relationship between the cost of cooling water intake structure control technology and the environmental benefits associated with its use. EPA requests comment on the relationship of costs to environmental benefits of this proposed rule.

C. What Is the Proposed Role of Restoration and Trading?

1. What Is the Proposed Role of Restoration?

Under today's proposed rule, consistent with the Phase II regulation, EPA would provide Phase III existing facilities with the option to use restoration under compliance alternatives § 125.103(a)(2), (3), and (5) where the performance of the restoration measures (the production and increase of fish and shellfish in the facility's waterbody or watershed, including maintenance of community structure and function), would be substantially similar to that which would have been achieved if the facility reduced its impingement mortality and entrainment through the use of design and construction technologies and/or operational measures, to meet the applicable performance standards. The role of restoration under this proposed rule is to provide additional flexibility to facilities in complying with the rule by eliminating or significantly offsetting the adverse environmental impact caused by the operation of a cooling water intake structure. Restoration measures that increase fish and shellfish in an impacted waterbody or watershed and would result in performance substantially similar to that which would otherwise be achieved through reductions in impingement mortality and entrainment further the goal of minimizing adverse environmental impact while offering additional flexibility to both permitting authorities and facilities. Restoration measures may include such activities as removal of barriers to fish migration, reclamation of degraded aquatic organism habitat, or stocking of aquatic organisms.

Restoration measures have been used at existing facilities as one of many tools to implement section 316(b) on a case-by-case, best professional judgment basis to compensate for the death and injury of fish and other aquatic organisms caused by the cooling water intake structure. Under today's proposed rule, a Phase III existing facility could utilize restoration measures either in lieu of or as a supplement to design and construction technologies and/or operational measures. For example, a facility could demonstrate to the Director that velocity controls are the most feasible technology choice for the facility but that, when used on their own, the velocity controls are insufficient to meet the applicable performance standards at § 125.103(b). The facility could then, in conjunction with the use of velocity controls, implement restoration measures to increase the fish and shellfish productivity of the waterbody in order to meet the performance standards at § 125.103(b). Another facility could demonstrate to the Director that restoration measures alone achieve the greatest compliance with the performance standards. A facility could alternatively request a site-specific determination of best technology available under § 125.103(a)(5) and use restoration measures to meet the alternate requirements. Facilities that are currently utilizing restoration measures to comply with their existing section 316(b) requirements may use these measures to comply with the performance standards at § 125.103(b) or site-specific requirements at § 125.103(a)(5). However, restoration measures that are required under other statutory provisions or regulations (e.g., CWA section 404) could not be used to comply with today's proposed rule.

Facilities that propose to use restoration measures would need to demonstrate to the Director that they evaluated the use of design and

[40] See 118 Cong. Rec 33,762 (1972), reprinted in 1 Legislative History of the Water Pollution Control Act Amendments of 1972, at 264 (1973)(Statement of Representative Don H. Clausen).

construction technologies and operational measures and determined that the use of restoration measures is appropriate because meeting the applicable performance standards or requirements through the use of other technologies is less feasible, less cost-effective, or less environmentally desirable than meeting the standards in whole or in part through the use of restoration measures. Facilities also would need to demonstrate that the restoration measures they plan to implement, alone, or in combination with design and construction technologies and/or operational measures, would produce ecological benefits (production of fish and shellfish) at a level that is substantially similar to the level that would be achieved through compliance with the applicable impingement mortality and/or entrainment performance standards under § 125.103(b), or alternative site-specific requirements under § 125.103(a)(5). In other words, restoration measures would have to replace the fish and shellfish lost to impingement mortality and entrainment to the extent the loss would have been reduced by otherwise applicable requirements, either as a substitute or as a supplement to reducing impingement mortality and entrainment through design and control technologies and/or operational measures. While the species makeup of the replacement fish and shellfish would not have to be exactly the same as that of the impingement mortality and entrainment losses, the Director would have to make a determination that the net effect is to produce a level of fish and shellfish in the waterbody that is ''substantially similar'' to that which would result from meeting the performance standards through design and construction technologies and/or operational measures alone. The proposed rule would require that a facility use an adaptive management method for implementing restoration measures because the performance of restoration projects must be regularly monitored and potentially adjusted to ensure the projects achieve their objectives (*see* 67 FR 17146–17148 and 68 FR 13542).

The proposed rule also would require that restoration projects which replace the lost fish and shellfish with a different species mix (''out of kind'' restoration) be based on a watershed approach to restoration planning. The boundaries of a ''watershed'' should be guided by the cataloging unit of the ''Hydrologic Unit Map of the United States'' (USGS, 1980), although it may be appropriate to use another watershed or waterbody classification system developed at the State or local level if such a system compares favorably in level of detail. For example, in coastal systems that support migratory fish, a coastal waterbody that transects a number of watersheds may be the most appropriate unit for planning restoration.

Legal Authority for Restoration

While the Phase I rule also authorized use of restoration measures, today's proposed rule includes additional regulatory controls on the use of restoration measures to ensure that they are used appropriately by existing facilities to comply with the applicable performance requirements or site specific alternative requirements. For example, as described above, restoration measures are authorized only after a facility demonstrates to the permitting authority that it has evaluated other design and construction technologies and operational measures and determined that they are less feasible, less cost effective, or less environmentally desirable than meeting the performance standards or alternative site-specific requirements in whole or in part through the use of restoration measures. The facility must also demonstrate that the proposed restoration measures will produce ecological benefits (*i.e.,* the production of fish and shellfish for the facility's waterbody or watershed, including maintenance of community structure and function) at a level that is substantially similar to the level a facility would achieve through compliance with the applicable performance standards or alternative site-specific requirements. Further, the permitting authority must review and approve the restoration plan to determine whether the proposed restoration measures will meet the applicable performance standards or site specific alternative requirements. Consequently, the restoration provisions of today's proposed rule are designed to minimize adverse environmental impact to a degree that is comparable to the other technologies on which the rule is based.

The use of restoration to meet the requirements of section 316(b) is consistent with the goals of the Clean Water Act; measures that restore fish and shellfish to compensate for those that are impinged and entrained further the objective of the Clean Water Act ''to restore, maintain, and protect the biological integrity of the nation's waters.'' 33 U.S.C. 1251(a) (emphasis added). It is also consistent with EPA's and States' past practices in implementing section 316(b) in individual permit decisions. For at least twenty years, EPA and States have authorized existing facilities to comply with section 316(b) requirements, at least in part, through the use of restoration measures. For example, the Chalk Point Generating Station, located on the Patuxent River in Prince George's County, Maryland constructed a fish rearing facility in partial compliance of its section 316(b) obligations (DCN 1–5023–PR).

Although the United States Court of Appeals for the Second Circuit recently remanded the portion of EPA's Phase I new facility rule that authorized restoration measures to meet that rule's requirements, EPA believes that portion of the decision should not apply to this Phase III proposed rulemaking. Indeed, the Second Circuit explicitly stated that ''[i]n no way [does it] mean to predetermine the factors and standard applicable to Phase II and III of the rulemaking.'' *Riverkeeper* v. *EPA,* slip op. at 12, note 13 (2nd Cir. Feb. 3, 2004). This is probably because there are important differences between new and existing facilities that warrant interpreting section 316(b) more broadly to give existing facilities additional flexibility to comply with section 316(b). As noted above, restoration measures have been used to comply with section 316(b) limits at existing facilities for several years because of the more limited availability of other technologies for existing facilities. Costs to retrofit an existing facility to install a ''hard'' technology can be much higher than costs to install one at the time a facility is constructed, and those costs can vary considerably from site to site. Thus, the range of technologies that are ''available'' to existing facilities to meet the performance standards is narrower than the range of technologies available to new facilities.

In recognition of the vast differences between existing and new facilities, Congress established separate sections in the Clean Water Act for establishing discharge limitations on existing and new facilities. Effluent limitations guidelines for existing facilities are established under sections 301 and 304, whereas new source performance standards are established under section 306. Those sections set out two distinct sets of factors for developing effluent limitations guidelines for existing facilities and new source performance standards for new facilities. Notably, there are only two factors explicitly stated in section 306 for the Administrator to consider in establishing new source performance standards—cost and non-water quality

impacts, whereas for existing facilities Congress calls upon EPA to consider a much broader range of factors in section 304(b)(2)(b): the age of equipment and facilities involved, the process employed, the engineering aspects * * * of various types of control techniques, process changes, the cost of achieving such effluent reduction, non-water quality environmental impacts (including energy requirements), and such other factors as [EPA] deems appropriate. This list reflects the wide range of facility characteristics and circumstances that can influence the feasibility and availability of a particular technology across a particular industry. Existing facilities generally face more and different problems than new facilities because of the technological challenges and high costs associated with retrofitting as compared to building a new facility. Indeed, by including the phrase ''and such other factors as [EPA] deems appropriate,'' Congress made certain that EPA would have sufficient flexibility in establishing limitations for existing facilities to consider all relevant factors. For several other reasons, EPA believes the Second Circuit decision is not binding on this Phase III proposed rule. First, section 316(b) requires the design of a cooling water intake structure to reflect the best technology available to ''minimize adverse environmental impact.'' The phrase ''minimize adverse environmental impact'' is not defined in section 316(b). For the Phase III proposed rule, EPA interprets this phrase to allow facilities to minimize adverse environmental impact by reducing impingement mortality and entrainment, or to minimize adverse environmental impact by compensating for those impacts after the fact. Section 316(b) does not explicitly state when the adverse environmental impact of cooling water structures must be minimized—that is whether they must be prevented from occurring in the first place or compensated for after the fact or where the minimization most occurs—at the point of intake or at some other location in the same watershed. Therefore, under Chevron, EPA is authorized to define ''minimize'' to authorize restoration at existing facilities to minimize the effects of adverse environmental impact.

In another context under the Clean Water Act, EPA has interpreted authority to ''minimize adverse effects'' as including authority to require environmental restoration. Section 404 of the CWA authorizes the Army Corps of Engineers to issue permits for discharges of dredged or fill material into waters of the United States. EPA was granted authority to establish regulations containing environmental guidelines to be met by the Corps in issuing section 404 permits. See CWA section 404(b)(1). Current regulations, in place since 1980, prohibit a discharge unless, among other requirements, all practicable steps are taken to avoid, minimize and mitigate for the environmental effects of a discharge. See 40 CFR 230.10. Of particular relevance here, the regulations require that steps be taken to ''minimize potential adverse effects of the discharge on the aquatic ecosystem'' (40 CFR 230.10(d)). EPA has specifically defined minimization steps to include environmental restoration. See 40 CFR 230.75(d) (''Habitat development and restoration techniques can be used to minimize adverse impacts and to compensate for destroyed habitat'').

Moreover, at the time of the Phase I litigation, EPA had not interpreted the term ''reflect'' in section 316(b), and therefore, the Second Circuit did not consider its meaning in determining whether restoration could be used as a design technology to meet the Phase I rule requirements. Section 316(b) requires that ''the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact.'' The term ''reflect'' is significant in two respects. First, it indicates that the design, location, construction and capacity of the cooling water intake structure itself must be based on the best technology available for such structures. This authorizes EPA to identify technologies that can be incorporated into the physical structure of the intake equipment. It also indicates that the choice of what actually is the best physical configuration of a particular cooling water intake structure can take into account, *i.e.*, reflect, other technologies—and their effects—that are not incorporated into the structure itself. For example, barrier nets are not incorporated into the physical design of the cooling water intake structure, but their use—and effectiveness—influences the physical design of the cooling water intake structure. Another relevant example is the technology known as ''closed-cycle'' cooling. Although this technology is physically independent of the cooling water intake structure, it directly influences decisions regarding the design capacity of the cooling water intake structure: as more cooling water is recycled, less needs to be withdrawn.

Both barrier nets and closed-cycle cooling are considered ''design'' technologies.'' Similarly, properly designed restoration measures can be best technologies available that can influence the design of the physical cooling water intake structure. To put it another way, for purposes of minimizing adverse environmental impact, requirements for cooling water intake structures reflect a variety of best technologies available, which EPA construes to include restoration measures. A dry cooling system is another example of a technology that although physically independent of the cooling water intake structure is nonetheless considered an acceptable method to minimize adverse environmental impacts. In fact, since a dry cooling system uses air as a cooling medium, it uses little or no water, dispensing altogether with the need for a cooling water intake structure.

EPA has discretion to characterize restoration measures as technologies for purposes of section 316(b). Section 316(b) does not define either the phrase ''cooling water intake structure'' or the term ''technology'' and, therefore, leaves their interpretation to EPA. EPA has defined the phrase cooling water intake structure in today's rule to mean the total physical structure and any associated waterways used to withdraw cooling water from waters of the United States. This definition embraces elements both internal and external to the intake equipment. EPA did not define the term technology in today's proposed rule, but looked for guidance to section 304(b), which the Second Circuit has recognized can help illuminate section 316(b). Section 301(b)(2) best available technology limitations are based on factors set forth in section 304(b). Section 304(b), while not using the term technology, discusses the ''application of the best control measures and practices achievable including treatment techniques, process and procedure innovations, operating methods, and other alternatives.'' This is a broad, nonexclusive list. Indeed, BAT effluent limitations guidelines under this authority have been based on a vast array of treatment techniques, operation practices (including chemical substitution), and management practices. *See* 40 CFR part 420 (effluent guidelines for concentrated animal feeding operations); 40 CFR part 430, subparts B & E (effluent guideline for pulp and paper industry). *See* also 62 FR 18504 (April 15, 1998).

Employing this broad concept of technology, in today's proposed rule EPA has determined that the design of cooling water intake structures may reflect technologies relating to the restoration of fish and shellfish in the

waters from which cooling water is withdrawn. Restoration is not included in the definition of ''design and construction technology'' in today's proposed rule so as to distinguish restoration from ''hard'' technologies for purposes of the proposed rule. Under the regulatory scheme of the proposed rule, restoration is treated differently than other technologies in several respects, all of which are to help ensure that restoration projects achieve substantially similar performance as design and construction technologies and/or operational measures. When these restoration technologies are used they must produce ecological benefits (the production of fish and shellfish for a facility's waterbody or watershed, including maintenance of community structure and function) at a level that is substantially similar to the level the facility would achieve by using other design and construction technologies and/or operational measures to achieve the applicable performance standards or alternative site-specific performance requirements in § 125.103. In other words, the operation of the cooling water intake structure together with these restoration technologies will achieve the overall performance objective of the statute: To minimize the adverse environmental impact of withdrawing cooling water. For facilities using this authority, their hardware decisions for the cooling water intake structure thus take into account—or reflect—the effects of restoration technology, as well as other technologies external to the intake structure itself.

EPA acknowledges that in 1982, when Congress was considering substantial amendments to the Clean Water Act, EPA testified in support of a proposed amendment to CWA section 316(b) that would have expressly authorized the use of restoration measures as a compliance option. According to the Second Circuit, this suggested that EPA may have interpreted section 316(b) at that time as not authorizing restoration measures to minimize the adverse environmental impact of cooling water intake structures. In EPA's view, the Second Circuit gave undue weight to that testimony, particularly because it was provided before the Supreme Court's decision in *Chevron U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984), which gave administrative agencies latitude to fill in the gaps created by ambiguities in statutes the agencies have been charged by Congress to implement. For at least twenty years, EPA and States have authorized existing facilities to comply with section 316(b) requirements, at least in part, through the use of restoration measures. Additionally, since 1982 EPA has gathered substantially more data to inform its judgment regarding cooling water intake structures, the environmental impact resulting from them, and various technologies available to reduce impingement mortality and entrainment. Finally, EPA notes that, in contrast to water quality based effluent limitations that are included in NPDES permits to meet water quality standards, the required performance of restoration measures under this proposed rule is not tied to conditions in the waterbody. Rather it is tied directly to the performance standards, just as is the performance of the other technologies that facilities may use to meet the standards. While the design and operation of restoration measures will necessarily be linked to conditions in the waterbody (as is also the case for ''hard'' technologies) the performance standards that restoration measures must meet are not.

2. What Is the Role of Trading in Today's Proposed Rule?

Under today's proposed rule, if a State demonstrates to the Administrator that it has adopted alternative regulatory requirements in its NPDES program that will result in environmental performance within a watershed that is comparable to the reductions of impingement mortality and entrainment that would otherwise be achieved under § 125.103, the Administrator must approve such alternative requirements (*see* § 125.100(c)). A trading program could be a part of these alternative regulatory requirements.

Trading under other EPA programs has been shown to provide opportunities for regulatory compliance at reduced costs. EPA's Office of Water's *Water Quality Trading Policy,* published in January 2003 (*see* DCN 6–5002), fully supports trading nutrients and sediment and adopts a case-by-case approach to evaluating proposals to trade other pollutants. Trading in the context of section 316(b) raises many complex issues, for example, how to establish appropriate units of trade and how to measure these units effectively given the dynamic nature of the populations of aquatic organisms subject to impingement mortality and entrainment. Should a State choose to propose a trading program under § 125.100(c), EPA would evaluate the State's proposal on a case-by-case basis to ensure the program complies with the regulatory requirement—that it will result in environmental performance within a watershed that is comparable to the reductions of impingement mortality and entrainment that would otherwise be achieved under the requirements established at § 125.103. For more information on approaches to trading under section 316(b) and considerations, see the Phase II proposed rule at 67 FR 17170–17173; April 9, 2002.

As in Phase II, questions have been raised by stakeholders in the context of EPA's section 316(b) rulemakings as to whether these proposed requirements would allow for trading of aquatic organisms for pollutant discharges. EPA is concerned that such a program may introduce comparability and implementation challenges that would be difficult to overcome, and therefore, EPA does not expect that such a program would work within the framework of today's proposed rule. In addition, EPA does not believe that it is possible at this time to quantify with adequate certainty the potential effects on ecosystem function, community structure, biodiversity, and genetic diversity of such trades, especially when threatened and/or endangered species are present. Based on the current state of the science in aquatic community ecology and ecological risk assessment, States wishing to develop trading programs in the context of section 316(b) would be better off focusing on programs based on metrics of comparability between fish and shellfish gains and losses among trading facilities, rather than the much more complex metrics that would be necessary for comparability among fish and shellfish losses on the one hand, and pollutant reductions on the other hand (69 FR 41609). EPA requests comment on the potential role of trading in the context of today's proposed rulemaking and possible approaches for developing a trading program.

VII. Implementation

As in Phase I and II, proposed section 316(b) requirements for Phase III existing facilities and new offshore oil and gas extraction facilities would be implemented through the NPDES permit program. Today's proposal would establish implementation requirements consistent with the Phase II final rule for Phase III existing facilities. This proposed rule would also establish implementation requirements for new offshore oil and gas extraction facilities that are generally consistent with Phase I requirements. Today's proposal would establish application requirements for Phase III existing facilities under 40 CFR 122.21 and proposed § 125.104, monitoring requirements under

proposed § 125.105, and record keeping and reporting requirements under proposed § 125.106. For new offshore oil and gas extraction facilities, today's proposal would establish application requirements consistent with 40 CFR 122.21 and proposed § 125.136, monitoring requirements under proposed § 125.137, and record keeping and reporting requirements consistent with proposed § 125.138. The proposed regulations also require the Director to review application materials submitted by each regulated facility and include monitoring and record keeping requirements in the permit (§ 125.107, § 125.139).

A. When Would the Proposed Rule Become Effective?

If promulgated as proposed, this proposed rule would become effective 60 days after the final rule is published in the **Federal Register.** Phase III existing facilities subject to today's proposed rule would need to comply with the Subpart K requirements when an NPDES permit containing requirements consistent with Subpart K is issued to the facility. Under existing NPDES program regulations, this would occur when an existing NPDES permit is reissued or, when an existing permit is modified or revoked and reissued. For facilities whose permits are expiring, EPA recognizes that facilities will need a reasonable time period to conduct baseline studies and develop and implement an appropriate suite of control technologies and this is provided for in § 125.104(a)(2)(ii). Under today's proposed rule, new offshore oil and gas extraction facilities would need to comply with the Subpart N requirements when an NPDES permit containing requirements consistent with Subpart N is issued to the facility (§ 125.132).

B. What General Information Would I Be Required To Submit to the Director When I Apply for My Reissued NPDES Permit?

The NPDES regulations that establish the application process at § 122.21 generally require that facilities currently holding a permit submit information and data 180 days prior to the end of the permit term, which is five years. Under today's proposed rule, Phase III existing facilities and new offshore oil and gas extraction facilities would be required to submit the information that is required under § 122.21 of today's proposed rule with their application for permit issuance or reissuance.

Today's proposed rule would modify regulations at § 122.21 to require existing Phase III facilities and new offshore oil and gas extraction facilities to prepare and submit some of the same information required for new Phase I and existing Phase II facilities. The proposed application requirements would require owners or operators of all Phase III existing facilities to submit two general categories of information when they apply for a reissued NPDES permit. The general categories of information would include (1) physical data to characterize the source waterbody in the vicinity where the cooling water intake structure(s) is/are located, and (2) data to characterize the design and operation of the cooling water intake structures. As in Phase II, Phase III existing facilities would not be required to submit the Source Water Baseline Biological Characterization Data required under § 122.21(r)(4). However, new offshore oil and gas extraction facilities may be required to submit the Source Water Baseline Biological Characterization Data depending on whether they are fixed or non-fixed facilities. Non-fixed facilities would be exempt from the requirement. Specific data requirements for the Source Water Baseline Biological Characterization Data are described later in this section. Studies to be submitted by both Phase III existing facilities and new offshore oil and gas extraction facilities are described below.

1. Source Water Physical Data (§ 122.21(r)(2))

Under the requirements at § 122.21, Phase III existing facilities and new offshore oil and gas extraction facilities subject to this proposed rule are required to provide the source water physical data specified at § 122.21(r)(2) in their application for a reissued permit. These data are needed to characterize the facility and evaluate the type of waterbody and species potentially affected by the cooling water intake structure. The Director would use this information to evaluate the appropriateness of the design and construction technologies proposed by the applicant.

The applicant for an existing facility or a new fixed offshore oil and gas extraction facility would be required to submit the following specific data: (1) A narrative description and scale drawings showing the physical configuration of all source waterbodies used by the facility, including areal dimensions, depths, salinity and temperature regimes, and other documentation; (2) an identification and characterization of the source waterbody's hydrological and geomorphological features, as well as the methods used to conduct any physical studies to determine the intake's zone of influence and the results of such studies; and (3) locational maps. For new non-fixed (mobile) offshore oil and gas extraction facilities this provision requires only some of the location information and not the source water physical data required for Phase III existing facilities and new fixed offshore oil and gas extraction facilities.

EPA recognizes that mobile facilities may not always know where they will be operating during the permit term, and the requirement in (r)(2)(iv) is not meant to restrict them only to locations identified in the permit application. However, EPA expects that permit applicants will provide, based on available information, their best estimate as to where they will be operating during the permit term, at whatever level of detail they can. EPA requests comment on this requirement.

2. Cooling Water Intake Structure Data (§ 122.21(r)(3))

Phase III existing facilities and new offshore oil and gas extraction facilities would be required to submit the cooling water intake structure data specified at § 122.21(r)(3) to characterize the cooling water intake structure and evaluate the potential for impingement and entrainment of aquatic organisms. Note that § 122.21(r)(3)(ii)—latitude and longitude of each intake structure—would not be applicable to non-fixed (mobile) offshore oil and gas extraction facilities. Information on the design of the intake structure and its location in the water column would allow the permit writer to evaluate which species or life stages would potentially be subject to impingement mortality and entrainment. A diagram of the facility's water balance would be used to identify the proportion of intake water used for cooling, make-up, and process water. The water balance diagram also provides a picture of the total flow in and out of the facility, allowing the permit writer to evaluate compliance with the performance standards or requirements.

The applicant would be required to submit the following specific data: (1) A narrative description of the configuration of each of its cooling water intake structures and where they are located in the waterbody and in the water column; (2) latitude and longitude in degrees, minutes, and seconds for each of its cooling water intake structures (not applicable to new non-fixed (mobile) offshore oil and gas extraction facilities); (3) a narrative description of the operation of each of the cooling water intake structures, including design intake flows, daily

hours of operation, number of days of the year in operation, and seasonal operation schedules, if applicable; (4) a flow distribution and water balance diagram that includes all sources of water to the facility, recirculating flows, and discharges; and (5) engineering drawings of the cooling water intake structure.

3. Cooling Water System Description (§ 122.21(r)(5)) (Phase III Existing Facilities Only)

Phase III existing facilities would be required to submit the cooling water system data specified at § 122.21(r)(5) to characterize the operation of cooling water systems and their relationship to the cooling water intake structure(s) at the facility. They would also be required to submit a narrative description of the proportion of design intake flow that is used in the system, the number of days of the year that the cooling water system is in operation, and any seasonal changes in the operation of the system, if applicable. The facility would also submit design and engineering calculations prepared by a qualified expert, such as a professional engineer, and supporting data to support the narrative description. This information would be expected to be used by the applicant and the Director in determining the appropriate standards that can be applied to the Phase III facility.

C. Phase III Existing Facility Implementation

In this proposed rule, a Phase III existing facility as defined by any of the three co-proposed options would choose one of the following five compliance alternatives for establishing best technology available for minimizing adverse environmental impact at the site (*see* § 125.103(a)(1–5)):

(1) Demonstrate that it has reduced its flow commensurate with a closed-cycle recirculating system and therefore already meets the performance standards to reduce impingement mortality and entrainment. Or, a facility may demonstrate that it has already reduced its design intake velocity to 0.5 feet per second and therefore meets the performance standards to reduce impingement mortality only;

(2) Demonstrate that existing design and construction technologies, operational measures, and/or restoration measures already meet the performance requirements specified under § 125.103(b) and the restoration requirements in (c), as applicable;

(3) Demonstrate that it has selected and installed design and construction technologies, operational measures, and/or restoration measures that will, in combination with any existing design and construction technologies, operational measures, and/or restoration measures, meet the performance standards specified under § 125.103(b) and the restoration requirements specified in § 125.103(c), as applicable;

(4) Demonstrate that it has installed and properly operates and maintains an approved design and construction technology in accordance with § 125.108(a); or propose a technology for approval in accordance with § 125.108(b); or,

(5) Demonstrate that a site-specific determination of best technology available for minimizing adverse environmental impact is appropriate for its site in accordance with § 125.103(a)(5).

The application, monitoring, record keeping, and reporting requirements for each of these compliance alternatives are detailed in the following sections.

1. As an Existing Phase III Facility, What Additional Information Would I Submit to the Director When I Apply for My Reissued NPDES Permit?

In addition to § 122.21 described above, the facility would be required to submit the information required under § 125.104, as appropriate. This information includes the Comprehensive Demonstration Study and its seven components as discussed in this section. The seven components include the following: Proposal for Information Collection; Source Waterbody Flow Information; Impingement Mortality and/or Entrainment Characterization Study; Technology Compliance and Assessment Information; Restoration Plan; Information to Support Site-specific Determination of Best Technology Available for Minimizing Adverse Environmental Impact; and Verification Monitoring Plan.

Under today's proposed rule, if a Phase III existing facility's permit expires before 4 years after the publication date of the final rule, the facility may request that the Director establish a schedule for the facility to submit the information required as expeditiously as practicable, but not later than 3 years and 180 days after publication of the final rule. Between the time the facility's existing permit expires and the time an NPDES permit containing requirements consistent with Subpart K is issued to the facility, the best technology available to minimize adverse environmental impact would continue to be based on the Director's best professional judgment.

The Proposal for Information Collection component of § 125.104 should be submitted to the Director for review and comment prior to the start of information collection activities. For a typical facility that plans to install a new technology, it is estimated that a facility would need to submit this Proposal for Information Collection about fifteen (15) months prior to the submission of the remainder of the required information, which in turn would need to be submitted about twenty-one (21) months prior to the expiration of its current permit. This approximate timing is based on the sequential Comprehensive Demonstration Study requirements and the estimated level of effort required to complete the studies and allow time for the Director's review and approval. The timing provided in this section is for illustrative purposes only and represents a schedule that the average facility may need to follow to meet the deadlines established in today's proposed rule. Some facilities may require more, or less time to perform the studies and prepare the application requirements. All facilities, except those that choose to comply with the proposed rule by reducing intake capacity to a level commensurate with a closed-cycle recirculating system in accordance with § 125.103(a)(1)(i), or by adopting an approved technology in accordance with § 125.103(a)(4) would submit a Proposal for Information Collection for review and comment by the Director (§ 125.104(a)(1)). Facilities that comply with impingement mortality requirements by reducing intake velocity to 0.5 feet per second or less in accordance with § 125.103(a)(1)(ii) will only need to submit a Comprehensive Demonstration Study, including a Proposal for Information Collection, for entrainment reduction requirements, if applicable. The Proposal for Information Collection requirements are detailed later in this section. Figure 1 presents an example of a possible time frame a facility may follow in preparing and submitting application components.

Following submission of the Proposal for Information Collection, the Director will review and provide comments on the proposal. During this time, the facility may proceed with planning, assessment, and data collection activities in fulfillment of Comprehensive Demonstration Study requirements. The Director is encouraged to provide comments expeditiously (*i.e.*, within 60 days) so the permit applicant can make

responsive modifications to its information gathering activities.

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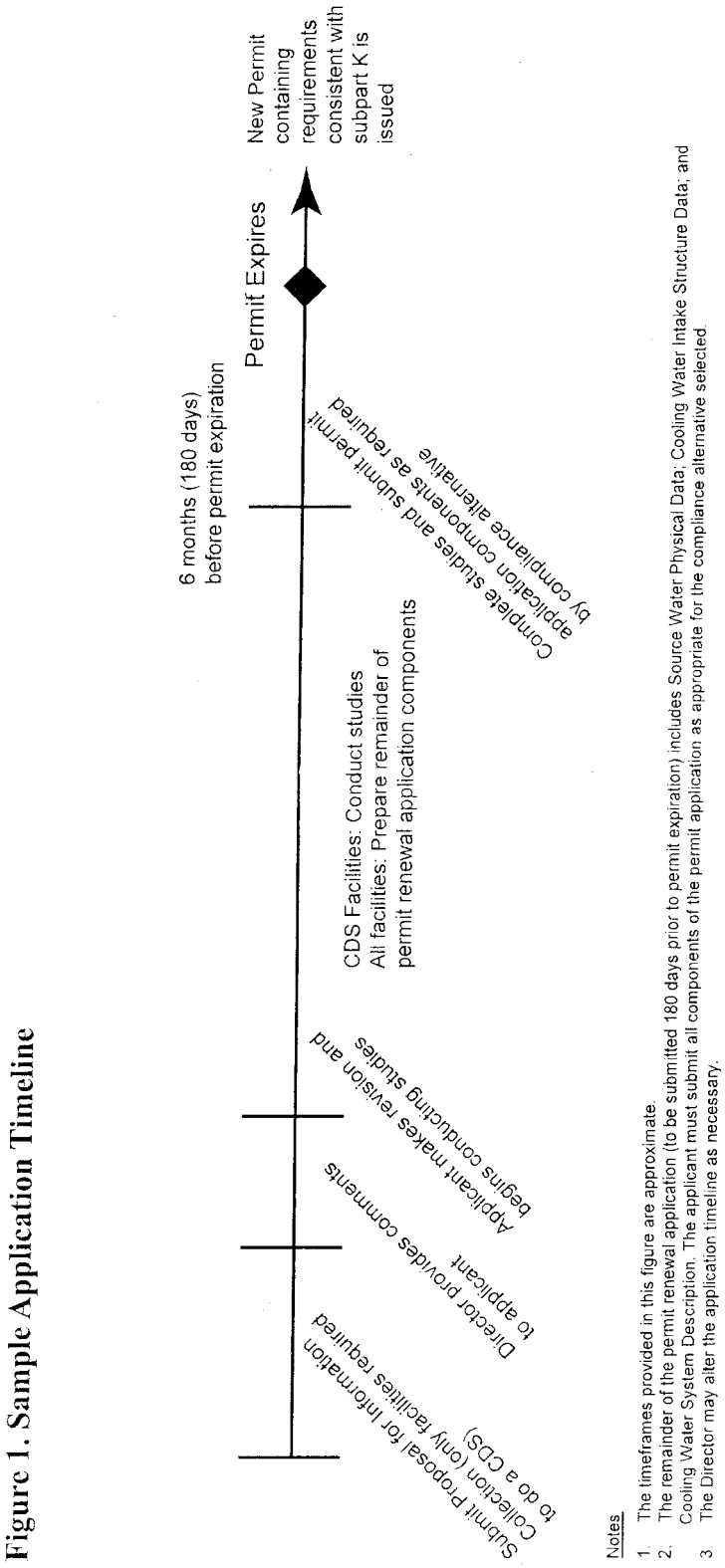

Figure 1. Sample Application Timeline

Notes

1. The timeframes provided in this figure are approximate.
2. The remainder of the permit renewal application (to be submitted 180 days prior to permit expiration) includes Source Water Physical Data; Cooling Water Intake Structure Data; and Cooling Water System Description. The applicant must submit all components of the permit application as appropriate for the compliance alternative selected
3. The Director may alter the application timeline as necessary.

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It is assumed that most facilities would need approximately one year to complete the studies outlined in the Proposal for Information Collection. These would be completed at least 180 days prior to the end of the current permit term, by which time the remainder of required application information would be submitted. If the facility believed it would require more than one year to complete studies described in the Proposal for Information Collection, the facility would be encouraged to consult with the Director.

After the first permit containing requirements consistent with Subpart K is issued, facilities may submit a request to their Director soliciting a reduced information collection effort for subsequent permit applications in accordance with § 125.104(a)(3), which allows facilities to demonstrate that the conditions at their facility and within the waterbody in which their intake is located remain substantially unchanged since their previous permit application. The request for reduced cooling water intake structure and waterbody application information would contain a list of and justification for each information item in § 122.21(r) and § 125.104(b) that has not changed since the previous permit application. The applicant would submit this request at least one year prior to the expiration of the current permit term and the Director is required to act on the request within 60 days.

The Director would review the information provided in the application including the information submitted in compliance with § 122.21 and § 125.104 and would confirm whether the facility should be regulated as an existing facility under these proposed regulations or as a new facility under regulations that were published on December 19, 2001 (66 FR 65256), and establish the appropriate requirements to be applied to the cooling water intake structure(s). Following review and approval of the permit application, the Director would develop a draft permit for public notice and comment. The comment period would allow the facility and other interested parties to review the draft permit conditions and provide comments to the Director. The Director would consider all public comments received on the draft permit and would develop a final permit based upon the application studies submitted and other information submitted during the comment period, as appropriate. The Director would incorporate the relevant requirements for the facility's cooling water intake structure(s) into the final permit.

The information required under § 125.104 would be identical under each of the three co-proposed regulatory options, with one exception. Under the regulatory option which defines facilities with design intakes flows 100 MGD or more located on tidal rivers, estuaries, or oceans or one of the Great Lakes as existing Phase III facilities, there would not be a requirement to collect the Source Waterbody Flow information described below, because this information is only relevant for facilities withdrawing water from freshwater rivers and streams or lakes and reservoirs. In addition, under this regulatory option there would not be any facilities required to meet only impingement mortality performance standards. Therefore, under this regulatory option all facilities except those that have met the applicable requirements in accordance with § 125.103(a)(1)(i) or § 125.103(a)(4) would be required to submit a Study for both the impingement mortality and entrainment reduction requirements, unless the facility had met the applicable requirements in § 125.103(a)(1)(ii), in which case it would be required to submit a Study for entrainment only. The following describes the proposed application requirements in more detail.

a. Comprehensive Demonstration Study (§ 125.104(b))

Proposed application requirements at § 125.104 would require all existing facilities except those deemed to have met the performance standard in § 125.103(a)(1) (reduced intake capacity to a level commensurate with the use of a closed-cycle, recirculating cooling water system, or for facilities with impingement requirements only, reduce intake velocity to 0.5 feet per second or less) to perform and submit to the Director the results of a Comprehensive Demonstration Study, including data and detailed analyses to demonstrate that the facility will meet applicable requirements contained in § 125.103(b) or established pursuant to § 125.103(a)(5).

The proposed Comprehensive Demonstration Study has seven components.

- Proposal for Information Collection;
- Source Waterbody Flow Information;
- Impingement Mortality and/or Entrainment Characterization Study;
- Technology and Compliance Assessment Information;
- Restoration Plan;
- Information to Support Site-specific Determination of Best Technology Available for Minimizing Adverse Environmental Impact; and
- Verification Monitoring Plan.

All Phase III existing facilities would not be required to submit each of these components of the Comprehensive Demonstration Study. Rather, required submittals for a facility would depend on the compliance alternative selected. All Phase III existing facilities, except those deemed to have met the performance standard in accordance with § 125.103(a)(1) or § 125.103(a)(4), would be required to submit a Proposal for Information Collection; Source Waterbody Flow Information whenever the intake is on a freshwater river or stream or a lake or reservoir; an Impingement Mortality and/or Entrainment Characterization Study; Technology and Compliance Assessment Information; and a Verification Monitoring Plan. Facilities complying in accordance with § 125.103(a)(4) would be required to submit Technology and Compliance Assessment Information and a Verification Monitoring Plan. Only those Phase III existing facilities that propose to use restoration measures in whole or in part to meet the performance standards in § 125.103(b) or site-specific requirements in § 125.103(a)(5) would be required to submit a Restoration Plan. Only those facilities that choose to demonstrate that a site-specific standard is appropriate for their site would be required to submit Information to Support Site-specific Determination of Best Technology Available for Minimizing Adverse Environmental Impact.

Proposal for Information Collection (§ 125.104(a))

Before conducting any studies, the facility would be required to submit to the Director for review and approval, a proposal stating what information would be collected to support the Comprehensive Demonstration Study (see § 125.104(b)(1)). This proposal would provide: (1) A description of the proposed and/or implemented technology(ies) and/or supplemental restoration measures to be evaluated; (2) a list and description of any historical studies characterizing impingement mortality and entrainment and/or the physical and biological conditions in the vicinity of the cooling water intake structures and their relevance to this proposed study. If the facility proposes to use existing data, it would demonstrate the extent to which the data are representative of current conditions and that the data were collected using appropriate quality assurance/quality control procedures;

(3) a summary of any past or ongoing (including voluntary) consultations with appropriate Federal, State, and Tribal fish and wildlife agencies that are relevant to this study and a copy of written comments received as a result of such consultation; and (4) a sampling plan for any new field studies proposed to be conducted in order to ensure that the facility has sufficient data to develop a scientifically valid estimate of impingement mortality and entrainment at the site. The sampling plan would document all methods and quality assurance/quality control procedures for sampling and data analysis. The sampling and data analysis methods proposed would be appropriate for a quantitative survey and would take into account the methods used in other studies performed in the source waterbody. The sampling plan would include a description of the study area (including the area of influence of the cooling water intake structure), and provide taxonomic identifications of the sampled or evaluated biological assemblages (including all life stages of fish and shellfish).

The proposed rule does not specify particular timing requirements for the information collection proposal, but does require review of the proposal by the Director. In general, EPA expects that it would be submitted well in advance of the other permit application materials, so that if the Director determined that additional information was needed to support the application, the facility would have time to collect this information, including additional monitoring as appropriate. In some cases, however, where the facility intends to rely on existing data and there has been no change in conditions at the site since the last permit renewal, a long lead time might not be necessary. This would most likely be the case for subsequent permit renewals following the first renewal after the Phase III requirements go into effect.

Source Waterbody Flow Information

Facilities under the co-proposed regulatory option that defines existing Phase III facilities as those with design intakes flows 100 MGD or more located on tidal rivers, estuaries, or oceans, or one of the Great Lakes would not have a requirement to submit Source Waterbody Flow Information. Under either of the other co-proposed options, Phase III existing facilities with cooling water intake structures that withdraw cooling water from freshwater rivers or streams, except those deemed to have met the performance standard in § 125.103(b) (in accordance with 125.103(a)(1)(i)), would be required to provide the mean annual flow of the waterbody and any supporting documentation and engineering calculations that allow a determination of whether they are withdrawing less than or greater than five (5) percent of the annual mean flow. This would provide information needed to determine which requirements would apply to the facility (see § 125.103(b)(1) and (2)). Facilities seeking compliance in accordance with § 125.103(a)(1)(ii) would need this information to determine whether they have impingement mortality and entrainment requirements, or impingement mortality requirements only. The documentation might include either publicly available flow data from a nearby U.S. Geological Survey (USGS) gauging station or actual instream flow monitoring data collected by the facility. The waterbody flow should be compared with the total design flow of all cooling water intake structures at the regulated facility.

Under the proposed requirements at § 125.103(b)(3), Phase III existing facilities with cooling water intake structures that withdraw cooling water from a lake or reservoir and that propose to increase the facility's design intake flow would be required to submit a narrative description of the waterbody's thermal stratification and any supporting documentation and engineering calculations to show that the increased flow meets the requirement not to disrupt the natural thermal stratification or turnover pattern (where present) of the source water except in cases where the disruption is determined, in consultation with Federal, State or Tribal fish and wildlife management agencies, to not adversely affect the management of fisheries. Typically, this natural thermal stratification would be defined by the thermocline, which may be affected to a certain extent by the withdrawal of cooler water and the discharge of heated water into the system. In cases where the lake or reservoir remains stratified, the Director may also consider changes in the relative size of the water layers due to the changes in withdrawals and any subsequent impacts (*e.g.*, change in dissolved oxygen, change in available habitat).

Impingement Mortality and/or Entrainment Characterization Study

The proposed regulations would require that the facility submit the results of an Impingement Mortality and/or Entrainment Characterization Study in accordance with § 125.104(b). This study would include: (1) Taxonomic identifications of those species of fish and shellfish and their life stages that are in the vicinity of the cooling water intake structure and are most susceptible to impingement and entrainment; (2) a characterization of these species of fish and shellfish and life stages, including a description of the abundance and temporal/spatial characteristics in the vicinity of the cooling water intake structure, based on the collection of a sufficient number of years of data to characterize annual, seasonal, and diel variations in impingement mortality and entrainment (*e.g.*, related to climate/weather differences, spawning, feeding and water column migration); and (3) documentation of the current impingement mortality and entrainment of all life stages of fish and shellfish at the facility and an estimate of impingement mortality and entrainment under the calculation baseline.

This documentation would include historical data that are representative of the current operation of the facility and of biological conditions at the site. Impingement mortality and entrainment samples to support the calculations required would be collected during periods of representative operational flows for the cooling water intake structure and the flows associated with the samples would be documented. In addition, this study would include an identification of species that are protected under Federal, State, or Tribal law (including threatened or endangered species) that might be susceptible to impingement and entrainment by the cooling water intake structure(s). The Director might coordinate a review of the list of threatened, endangered, or other protected species with the U.S. Fish and Wildlife Service, National Marine Fisheries Service, or other relevant agencies to ensure that potential impacts to these species have been addressed.

The calculation baseline is defined at § 125.102 as an estimate of impingement mortality and entrainment that would occur at the site assuming: (1) The cooling water intake system has been designed as a once-through system; (2) the opening of the cooling water intake structure is located at, and the face of the standard 3/8inch mesh traveling screen is oriented parallel to, the shoreline near the surface of the source waterbody; and (3) the baseline practices, procedures, and structural configuration are those that the facility would maintain in the absence of any structural or operational controls, including flow or velocity reductions, implemented in whole or in part for the purposes of reducing impingement mortality and entrainment. The facility

may also choose to use its current level of impingement mortality and entrainment as the calculation baseline. EPA has previously referred to this as the ''as-built approach'' (69 FR 41576).

Reductions in impingement mortality and entrainment from the calculation baseline as a result of any design and construction technologies and/or operational measures already implemented at the facility should be added to the reductions expected to be achieved by any additional design and construction technologies and operational measures that will be implemented in order to meet the applicable performance standards or site-specific requirements. In this case, the calculation baseline could be estimated by evaluating existing data from a facility nearby without impingement and/or entrainment control technology (if relevant) or by evaluating the abundance of organisms in the source waterbody in the vicinity of the intake structure that may be susceptible to impingement and/or entrainment. Additionally, if a portion of the total design intake flow is water withdrawn for a closed-cycle, recirculating cooling system (but flow is not sufficiently reduced to satisfy the compliance option in § 125.103(a)(1)(i)), such facilities would be able to use the reduction in impingement mortality and entrainment that is attributed to the reduction in flow in meeting the performance requirements in § 125.103.

The calculation baseline may be estimated using: historical impingement mortality and entrainment data from the facility or from another facility with comparable design, operational, and environmental conditions; current biological data collected in the waterbody in the vicinity of the cooling water intake structure; or current impingement mortality and entrainment data collected at the facility. A facility could also request that the calculation baseline be modified to be based on a location of the opening of the cooling water intake structure at a depth other than at or near the surface if it can demonstrate to the Director that the other depth would correspond to a higher baseline level of impingement mortality and/or entrainment.

Technology and Compliance Assessment Information

The Technology and Compliance Assessment Information required under § 125.104(b)(4) consists of two parts: (1) The Design and Construction Technology Plan; and (2) the Technology Installation and Operation Plan. If a facility plans to utilize the compliance alternative in § 125.103(a)(4), it need only submit the Technology Installation and Operation Plan (and the Verification Monitoring Plan under § 125.104(b).) If the facility plans to utilize the compliance alternative in § 125.103(a)(2) or (3) using design and construction technologies and/or operational measures (either existing or new), it would submit both the Design and Construction Technology Plan and the Technology Installation and Operation Plan. Note that facilities seeking a site-specific determination of best technology available in accordance with § 125.103(a)(5), would submit a Site-Specific Technology Plan in accordance with § 125.104(b) rather than a Design and Construction Technology Plan, as well as a Technology Installation and Operation Plan and the other studies discussed later in section VII.C.5, Alternative Site-Specific Requirements.

The Design and Construction Technology Plan would explain the technologies or operational measures selected by a facility to meet the requirements in § 125.103(a)(2) or (3). The Agency recognizes that selection of the specific technology or group of technologies for the site will depend on individual facility and waterbody conditions. Examples of appropriate technologies may include, but are not limited to, wedgewire screens, fine mesh screens, fish handling and return systems, barrier nets, aquatic filter barrier systems, and enlargement of the cooling water intake structure to reduce velocity. Examples of operational measures include, but are not limited to, seasonal shutdowns or reductions in flow, and continuous or more frequent rotation of traveling screens.

Information required as part of the Design and Construction Technology Plan would include the following: (1) A narrative description of the design and operation of all design and construction technologies and/or operational measures that have been or will be put into place to meet the performance standards for reduction of impingement mortality of those species most susceptible to impingement, and information that demonstrates the efficacy of those technologies and/or operational measures for those species; (2) a description of the design and operation of all design and construction technologies or operational measures that have been or will be put into place, to meet the performance standards for reduction of entrainment for those species most susceptible to entrainment, if applicable to the facility, and information that demonstrates the efficacy of those technologies and/or operational measures for those species; (3) calculations of the reduction in impingement mortality and/or entrainment of all life stages of fish and shellfish that would be achieved by the technologies and/or operational measures selected based on the Impingement Mortality and/or Entrainment Characterization Study in § 125.104(b); and (4) design and engineering calculations, drawings, and estimates to support the narrative descriptions required in the Design and Construction Technology Plan prepared by a qualified expert such as a professional engineer.

In determining compliance with any requirements to reduce impingement mortality or entrainment, the facility would assess the total reduction in impingement mortality and entrainment against the calculation baseline developed under the Impingement Mortality and/or Entrainment Characterization Study.

Under the Phase II final rule, power producing facilities with a capacity utilization rate of less than 15 percent are only required to meet the impingement mortality reduction requirements, based on EPA's determination that entrainment impacts below this threshold would be minimal. EPA defined the capacity utilization rate as the ratio between the average annual net generation of the power by the facility (in MW) and the total net capability of the facility to generate power (in MW) multiplied by the number of available hours during a year. Today's proposed rule does not contain an analogous provision for manufacturing facilities, as EPA has been unable to identify a similar threshold of operations below which impacts would be considered minimal. EPA requests comment on the availability of such a threshold that would result in lesser requirements for facilities that do not operate full time, thus minimizing burdens to these facilities while still protecting the source waterbody.

The Technology Installation and Operation Plan is required for all facilities that choose the compliance alternatives in § 125.103(a)(2), (3), (4), or (5), and propose to use design and construction technologies and/or operational measures (either existing or new) to meet performance standards or site specific requirements. Such facilities would submit the following information to the Director for review and approval: (1) A schedule for the installation and maintenance of any new design and construction technologies; (2) a list of the operational parameters that will be monitored, including the location and the

frequency at which they will be monitored; (3) a list of activities to be undertaken to ensure to the degree practicable the efficacy of the installed design and construction technologies and operational measures, and the schedule for implementing them; (4) a schedule and methodology for assessing the efficacy of any installed design and construction technologies and operational measures in achieving applicable performance standards, including an adaptive management plan for revising design and construction technologies and/or operational technologies if the assessment indicates that applicable performance standards are not being met; and (5) for facilities that select an approved technology in accordance with § 125.103(a)(4), documentation that appropriate site conditions (as specified by EPA or the Director in accordance with § 125.108) exist at the facility. In developing the schedule for installation and maintenance of any new design and construction technologies in item 1, the facility should schedule any downtime to coincide with otherwise necessary downtime (*e.g.*, for repair, overhaul, or routine maintenance of the) to the extent practicable. The Director should approve any reasonable scheduling provision included for this purpose. Those facilities that propose to use restoration measures in whole or in part would submit the Restoration Plan required at § 125.104(b)(5).

Today's proposed rule would require the Director to evaluate, using information submitted in the application, biennial status reports, and any other available information, the performance of any technologies, operational measures, and/or restoration measures the facility may have implemented in previous permit terms. Additional or different design and construction technologies, operational measures, and/or restoration measures may be required if the Director determines that the initial technologies, operational measures, and/or restoration measures selected and implemented will not meet the requirements of § 125.103, as provided in § 125.107. The proposed rule also requires that the permit contain a condition requiring the facility to reduce impingement mortality and entrainment (if applicable) commensurate with the efficacy of the installed design and construction technologies and/or operational measures. This is designed to ensure that technologies are operated and maintained to ensure their efficacy to the degree practicable, and not merely to meet the low end of the applicable performance standard range, if better performance is practicable.

The Technology Installation and Operation Plan is one of the most important pieces of documentation for implementing the requirements of this proposed rule. It serves to: (1) Guide facilities in the installation, operation, maintenance, monitoring, and adaptive management of selected design and construction technologies and/or operational measures; (2) provide a schedule and methodology for assessing success in meeting applicable performance standards and site-specific requirements; and (3) provide a basis for determining compliance with the requirements of § 125.103(a)(2)–(5). Facilities and Directors are encouraged to take appropriate care in developing, reviewing and approving the plan. Note that for facilities employing restoration measures, the Restoration Plan serves the same required functions.

Restoration Plan

EPA proposes restoration measures as one of several technologies that may be employed, alone or in combination with others, to minimize adverse environmental impact at existing facilities. The consideration of restoration measures is relevant to the section 316(b) determination of the requisite design of cooling water intake structures because restoration measures help minimize the adverse environmental impact attributable to such structures. Phase III existing facilities may use restoration measures that produce and/or result in levels of fish and shellfish in the facility's waterbody or watershed that are substantially similar to those that would result through compliance with the applicable performance standards or alternative site-specific requirements. In order to employ restoration measures, the facility would demonstrate to the Director that it has evaluated the use of design and construction technologies and/or operational measures and determined that the use of restoration measures is appropriate because meeting the applicable performance standards or site-specific requirements through the use of design and construction technologies and/or operational measures alone is less feasible, less cost-effective or less environmentally desirable than meeting the standards in whole or in part through the use of restoration measures. Facilities would also demonstrate to the Director that the restoration measures, alone or in combination with any selected design and construction technologies and/or operational measures, will produce ecological benefits and maintain fish and shellfish in the waterbody, including community structure and function, at a substantially similar level to that which would be achieved by meeting the applicable performance standards at § 125.103(b) or the site-specific requirements developed pursuant to § 125.103(a)(5).

To help all parties review the proposed or existing restoration measures and to help ensure adequate performance of those measures, § 125.104(b) would require facilities proposing to use restoration measures to submit the following information in a Restoration Plan with their applications to the Director for review and approval. In the submittal, the facility would address species identified, in consultation with Federal, State, and Tribal fish and wildlife management agencies with responsibility for fisheries and wildlife potentially affected by the facility's cooling water intake structures, as species of concern. The level of complexity of the Restoration Plan likely will be commensurate with the restoration measures considered or proposed.

First, the facility would be required to demonstrate that it has evaluated the use of design and construction technologies and/or operational measures and explain how it determined that the use of restoration measures would be more feasible, cost-effective, or environmentally desirable than meeting the applicable performance standards or site-specific requirements wholly through the use of design and construction technologies, and/or operational measures.

Second, the facility would be required to submit a narrative description of the design and operation of all restoration measures the facility has in place or has selected and proposes to implement to produce fish and shellfish. If the ecological benefits from an existing restoration project are required to compensate for some environmental impact other than the impact from impingement and entrainment by the cooling water intake structure (*e.g.*, a wetland created to satisfy section 404 of the Clean Water Act requirements), those ecological benefits should not be counted towards meeting the applicable performance standards or site-specific requirements. The narrative description should identify the species targeted under any restoration measures.

Third, the facility would be required to submit a quantification of the ecological benefits of the existing and/or proposed restoration measures. The facility would estimate the reduction in fish and shellfish impingement mortality and entrainment that would

be necessary to comply with applicable performance standards or site-specific requirements, using information from the Impingement Mortality and/or Entrainment Characterization Study and any other available and appropriate information. The facility would then calculate the production of fish and shellfish from existing and proposed restoration measures. The quantification would also include a discussion of the nature and magnitude of uncertainty associated with the performance of the restoration measures and a discussion of the time frame within which ecological benefits are expected to accrue from the restoration project.

Fourth, the facility would be required to provide design calculations, drawings, and estimates documenting that the proposed restoration measures, in combination with design and construction technologies and/or operational measures, or alone, will meet the requirements for production of fish and shellfish. Production of fish and shellfish as a result of relevant restoration measures already implemented at the facility should be added to the production expected to be achieved by the additional restoration measures. If the restoration measures address the same fish and shellfish species identified in the Impingement Mortality and/or Entrainment Characterization Study (in-kind restoration), the facility would be required to demonstrate that the restoration measures will produce a level of these fish and shellfish substantially similar to that which would result from meeting applicable performance standards or site-specific requirements. In this case, the calculations should include a site-specific evaluation of the suitability of the restoration measures based on the species that are found at the site. If the restoration measures address fish and shellfish species different from those identified in the Impingement Mortality and/or Entrainment Characterization Study (out-of-kind restoration), the facility would be required to demonstrate that the restoration measures produce ecological benefits substantially similar to or greater than those that would be realized through in-kind restoration. Such a demonstration should be based on a watershed approach to restoration planning and consider applicable multi-agency watershed restoration plans, site-specific peer-reviewed ecological studies, and/or consultation with appropriate Federal, State, and Tribal natural resource agencies. While both in-kind and out-of-kind restoration require a quantification of the levels of fish and shellfish the restoration measures are expected to produce, out-of-kind restoration could include a qualitative demonstration that these ecological benefits are substantially similar to or greater than those that would be realized through in-kind restoration, because different species are being produced that may not be directly comparable to those identified in the Impingement Mortality and/or Entrainment Characterization Study. The Director could require additional information from the facility in order to assess the results of the out-of-kind restoration (*e.g.*, biological data on species present, function of species in the community, etc.).

Fifth, the facility would be required to submit a plan utilizing an adaptive management method for implementing, maintaining, and demonstrating the efficacy of the restoration measures it has selected and for determining the extent to which restoration measures, or the restoration measures in combination with design and construction technologies and operational measures, have met the applicable performance standards or site-specific requirements. Adaptive management is a process in which a facility chooses an approach for meeting a project goal, monitors the effectiveness of that approach, and then, based on monitoring and any other available information, makes any adjustments necessary to ensure continued progress toward the project's goal. This cycle is repeated as necessary until the goal is met.

The adaptive management plan would include: (1) A monitoring plan that includes a list of the restoration parameters that the facility will monitor, the frequency at which they will be monitored, and the success criteria for each parameter; (2) a list of activities the facility will undertake to ensure the efficacy of the restoration measures, a description of the linkages between these activities and the items described in the monitoring plan, and an implementation schedule for the activities; and (3) a process for revising the restoration plan as new information, including monitoring data, becomes available, and if the applicable performance standards or site-specific requirements are not being met.

Sixth, the facility would be required to submit a summary of any past or ongoing consultation with Federal, State, and Tribal fish and wildlife management agencies on its use of restoration measures, including any written comments received as a result of such consultations.

Seventh, if requested by the Director, the facility would be required to conduct a peer review of items to be submitted as part of the Restoration Plan. Written comments from peer reviewers would be submitted to the Director and made available to the public as part of the permit application. Peer reviewers would be selected in consultation with the Director who may consult with EPA, and with Federal, State and Tribal fish and wildlife management agencies with responsibility for fish and wildlife potentially affected by the facility's cooling water intake structure(s). Peer reviewers would be required to have appropriate qualifications (*e.g.*, in the fields of geology, engineering and/or biology) depending upon the materials to be reviewed.

Finally, the facility would be required to include in the Plan a description of information to be included in a status report to the Director every two years. The proposed regulations at § 125.107(b) would require that this information be reviewed by the Director to determine whether the proposed restoration measures, in conjunction with (or in lieu of) design and construction technologies and/or operational measures, would meet the applicable performance standards or site-specific requirements, or, if the restoration is out-of-kind, would produce substantially similar ecological benefits (fish and shellfish) including maintenance or protection of community structure and function in the facility's waterbody or watershed.

Compliance Using an Approved Technology

Today's proposed rule would offer facilities the choice of adopting a protective, pre-approved design and construction technology, which would allow them to submit a significantly streamlined Comprehensive Demonstration Study. Section 125.108 lists one approved technology (wedgewire screens) and provides an opportunity for the Director to pre-approve other technologies.

If the facility chooses to comply with this compliance alternative, the facility would submit documentation to the Director that the facility meets the appropriate site conditions and the facility has installed and will properly operate and maintain submerged cylindrical wedgewire screen technology (as described in § 125.108(a)(1)) or other technologies as approved by the Director under § 125.108(b)). If the facility is subject to impingement mortality performance standards only, and plans to install

wedgewire screens with a maximum through-screen design intake velocity of 0.5 feet per second or less, the facility should choose the compliance alternative in § 125.103(a)(1)(i), and does not need to demonstrate that it meets the other criteria in § 125.104(a)(1) or prepare a Technology Installation and Operation Plan or Verification Monitoring Plan.

Facilities subject to entrainment performance standards seeking compliance under this alternative would submit a Technology Installation and Operation Plan and a Verification Monitoring Plan that address entrainment reduction, and document that all of the appropriate site conditions in § 125.108(a)(1) exist at their facility. To qualify for compliance using the cylindrical wedgewire screen technology, the facility would have to meet the following conditions: (1) The cooling water intake structure is located in a freshwater river or stream; (2) the cooling water intake structure is situated such that sufficient ambient counter-currents exist to promote cleaning of the screen face; (3) the maximum through-screen design intake velocity is 0.5 feet per second or less; (4) the slot size is appropriate for the size of eggs, larvae, and juveniles of all fish and shellfish to be protected at the site; and (5) the entire main cooling water intake flow is directed through the technology. Facilities should demonstrate that they meet these criteria in the Technology Installation and Operation Plan. Note the submerged cylindrical wedgewire screen technology is only pre-approved if the cooling water intake structure is, among other things, located in a freshwater river or stream (*see* § 125.108(a)). Therefore, this particular pre-approved technology would not apply under the co-proposed regulatory option that defines Phase III existing facilities as those with design intakes flows 100 MGD or more located on tidal rivers, estuaries, or oceans, or one of the Great Lakes.

In addition, any interested person could submit a request that a technology be approved for use in accordance with the compliance alternative in § 125.103(a)(4). If the Director approves, the technology may be used by all facilities that have similar site conditions under the Director's jurisdiction. To do this, the interested person would submit the following as required by § 125.108(b): (1) A detailed description of the technology; (2) a list of design criteria for the technology and site characteristics and conditions that each facility would need to have in order to ensure that the technology can consistently meet the appropriate impingement mortality and entrainment performance standards in § 125.103(b); and (3) information and data sufficient to demonstrate that all facilities under the jurisdiction of the Director can meet the applicable impingement mortality and entrainment performance standards in § 125.103(b) if the applicable design criteria and site characteristics and conditions are present at the facility.

EPA is proposing this compliance alternative in response to comments received under the Phase II proposed rule suggesting that EPA provide an additional, more streamlined compliance option under which a facility could implement certain specified technologies that are deemed highly protective in exchange for reducing the scope of the Comprehensive Demonstration Study. (*See,* 68 FR 13522, 13539; March 19, 2003). This approach was also endorsed by small entity representatives and the Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule for Cooling Water Intake Structures at Section 316(b) Phase III Facilities (DCN 7–0006). EPA is soliciting comments on other technologies that are equally protective and may be used to meet the performance requirements.

Information To Support Site-Specific Determination of Best Technology Available for Minimizing Adverse Environmental Impact

If a facility selects compliance alternative 5 (§ 125.103(a)(5)), it would be required to demonstrate that its costs of compliance under the compliance alternatives 3 or 4 (§ 125.103(a)(3) or (4)) would be significantly greater than the costs considered by the Administrator for a similar facility in establishing the applicable performance standards, or that its cost of compliance under alternatives 3 and 4 would be significantly greater than the benefits of complying with the applicable performance requirements. Depending on the approach taken, a facility would be required to complete the Site-Specific Technology Plan, the Comprehensive Cost Evaluation Study, and possibly the Benefits Valuation Study. These study requirements are discussed later in section VII.C.5, Alternative Site-Specific Requirements.

Verification Monitoring Plan

Section 125.104(b) would require all Phase III existing facilities, except those deemed to have met the performance standard in § 125.103(a)(1), to submit a Verification Monitoring Plan to measure the efficacy of the implemented design and construction technologies and/or operational measures. The plan would include a monitoring study lasting at least two years to verify the full-scale performance of the proposed or already implemented technologies and of any additional operational measures. The plan would be required to describe the frequency of monitoring and the parameters to be monitored and the bases for determining these. The Director would use the verification monitoring results to confirm that the facility is meeting the level of impingement mortality and/or entrainment reduction expected and that fish and shellfish are being maintained at the level expected (as required in § 125.105). Verification monitoring would be required to begin once the technologies and/or operational measures are implemented and continue for a sufficient period of time (but at least two years) to demonstrate that the facility is reducing impingement mortality and/or entrainment to the level of reduction required.

2. How Would the Director Determine the Appropriate Cooling Water Intake Structure Requirements?

The Director's first step would be to determine whether the facility is covered by this proposed rule. If the answer to all the following questions is yes, the facility would be required to comply with the requirements of this proposed rule.

(1) Is the facility a point source?

(2) Is the facility an existing facility other than a Phase II existing facility?

(3) Does the facility use at least 25 percent of water withdrawn exclusively for cooling purposes, measured on an average annual basis? and

(4) Does the facility use, or propose to use, a cooling water intake structure (including a cooling water intake structure operated by an independent supplier) that meets the total design intake flow/source waterbody threshold as specified under each of the three co-proposed regulatory options to withdraw cooling water from waters of the United States?

If a facility is a point source that uses a cooling water intake structure and has or is required to have an NPDES permit, but does not meet the applicability requirements in today's proposed rule, it would continue to be subject to permit conditions implementing section 316(b) of the Clean Water Act set by the Director on a case-by-case basis, using best professional judgment.

The Director's second step would be to determine whether the facility proposes to comply: By demonstrating

that its existing design and construction technologies, operational measures, or restoration measures meet the proposed performance standards; by implementing design and construction technologies, operational measures, or restoration measures that, in combination with existing technologies and operational measures, meet the proposed performance standards; by using an approved technology; or by seeking a site-specific determination of best technology available to minimize adverse environmental impact (*see* § 125.103(a)).

If a facility selects compliance alternative 1 (§ 125.103(a)(1)), and it demonstrates that it has reduced its flow commensurate with a closed-cycle recirculating system and therefore already meets the performance standards to reduce impingement mortality and entrainment, the Director would only have to verify that this is indeed true; no additional requirements are necessary. Under compliance alternative 1, a facility may demonstrate that it has already reduced its design intake velocity to 0.5 feet per second and therefore meets the performance standards to reduce impingement mortality only. Again the Director would only need to verify the design intake velocity and no further requirements would be necessary.

Under compliance alternative 2 (§ 125.103(a)(2)), in which a Phase III existing facility chooses to demonstrate that its existing design and construction technologies, operational measures, or restoration measures meet the proposed performance standards, the Director would need to verify that the existing facility meets the impingement mortality and entrainment reduction requirements.

To verify that existing controls meet the impingement mortality and entrainment reduction requirements in the proposed rule, the Director would need to: (1) Verify the facility's baseline calculation; (2) confirm the location of the facility's cooling water intake structure(s); (3) verify the withdrawal percentage of mean annual flow if applicable; (4) review impingement mortality and/or entrainment rates or estimates; and (5) consider any use of restoration. These same steps also would be part of determining requirements under other compliance alternatives as discussed below.

The Director would initially review and verify the calculation baseline estimate submitted by the facility under § 125.104(b). This estimate would need to be consistent with the proposed definition of the term ''calculation baseline'' and be representative of current biological conditions at the facility. The Director would then review the information that the facility provides to validate the source waterbody type in which the cooling water intake structure is located (freshwater river or stream; lake or reservoir; or estuary, tidal river, ocean, or Great Lake). The Director would review the supporting material the applicant provided in the permit application to document the physical placement of the cooling water intake structure. For existing facilities with one or more cooling water intake structures located in a freshwater river or stream, the Director would need to determine whether the facility withdraws more or less than five percent of the mean annual flow, which determines whether impingement mortality, or impingement mortality and entrainment controls would apply. For facilities with cooling water intake structures located on lakes or reservoirs, other than a Great Lake, for which the facility seeks to increase the design flow, the Director would need to determine whether the increased intake flow would disrupt the natural thermal stratification or turnover pattern of the source waterbody. In making this determination, the Director would need to consider anthropogenic factors that can influence the occurrence and location of a thermocline, and would need to coordinate with appropriate Federal, State, or Tribal fish and wildlife agencies to determine if any disruption adversely impacts the management of the fisheries. Both of these determinations would be based on the source waterbody flow information required under § 125.104(b).

For Phase III existing facilities that have in place existing restoration measures that meet the requirements of § 125.103(b), the Director would review the evaluation of the current restoration measures submitted under § 125.104(b). The Director could gather additional information and solicit input for the review from appropriate fishery management agencies as necessary. The Director would need to determine whether the current measures would maintain the fish and shellfish in the waterbody at comparable levels to those that would be achieved under § 125.103, as well as review and approve the proposed Restoration Plan required in § 125.104(b).

Finally, the Director would need to review impingement and/or entrainment data or estimates to determine whether in-place controls achieve the performance standards proposed for the different categories of source waterbodies. This step would involve comparing the calculation baseline with the impingement and/or entrainment data or estimates provided as part of the Comprehensive Demonstration Study and the Impingement Mortality and/or Entrainment Characterization Study requirements under § 125.104(b).

If the Director determines that the existing technologies, operational measures, or supplemental restoration measures employed do not achieve compliance with the applicable performance standards, the Director would issue a permit requiring additional measures to achieve such compliance, based on the information submitted in the Comprehensive Demonstration Study (§ 125.107(b)(1)). If such studies are approved and a permit is issued on that basis, but the Director later determines, based on the results of subsequent monitoring, that the technologies, operational measures, and supplemental restoration measures did not meet the performance standards, the Director would require the existing facility to implement additional technologies and operational measures as necessary to meet the rule requirements. In general, this would occur at the next renewal of the permit. The Director would also review the facility's Verification Monitoring Plan and/or Restoration Plan (as appropriate) for post-operational monitoring to demonstrate that the technologies and/or restoration measures are performing as predicted.

Under compliance alternative 3 (§ 125.103(a)(3)), the same general steps would be followed as described above to assess compliance of existing controls with applicable performance standards except that under this alternative, the Phase III existing facility would be required to demonstrate that the technologies and measures identified would meet (rather than currently meet) the applicable performance standards. This review would also be based on data submitted in the Comprehensive Demonstration Study required under § 125.104(b).

For facilities seeking compliance under compliance alternative 4 (§ 125.103(a)(4)), through the use of an approved technology, the Director would review the Technology Installation and Operation Plan and Verification Monitoring Plan.

These same basic steps described under compliance alternatives 2 and 3 would also apply to facilities seeking to comply under compliance alternative 5 (§ 125.103(a)(5)); however, the Director would be required to make two additional determinations under this option, including whether the facility meets one of the applicable cost tests

and what alternative requirements are justified in light of the significantly greater costs. Phase III existing facilities seeking to comply under this option would be required to submit a Comprehensive Cost Evaluation Study under § 125.104(b), which includes data that document the cost of implementing design and construction technologies, operational measures, and/or restoration measures to meet the otherwise applicable performance standards in § 125.103(b). The Director would need to review these data, including detailed engineering cost estimates, and compare these with the costs the Agency considered in establishing these requirements for a like Phase III facility. Where the Director finds that the facility's cost of implementation is significantly greater than those considered during rule development, he or she would approve site-specific requirements and could approve alternative technologies or operational measures. Such alternative technologies or operational measures could be those proposed by the facility in the Site-Specific Technology Plan or Restoration Plan, but less protective requirements would have to be justified by the significantly greater costs.

Where a Phase III existing facility seeks site-specific requirements based on facility costs that are significantly greater than the environmental benefits of compliance, the facility would also be required to submit a Benefits Valuation Study (along with the Comprehensive Cost Evaluation Study). The Director would review the benefits valuation, including a narrative description of non-quantified benefits, to determine whether it fully values the benefits of meeting the applicable performance standards, as required in § 125.104(b), and whether the facility's cost of implementation is significantly greater than the environmental benefits of complying with the requirements of § 125.103(b). If the Director determines that the compliance costs are significantly greater than the environmental benefits, the Director would approve site-specific requirements and could approve alternative technologies or operational measures. Such alternative technologies or operational measures could be those proposed by the facility in the Site-Specific Technology Plan and/or Restoration Plan, but less protective requirements would have to be justified by the significantly greater costs. EPA is interested in ways to decrease application review time and is requesting comments on how to make this process both efficient and effective.

3. What Would I Be Required To Monitor?

Section 125.105 of today's proposed rule provides that Phase III existing facilities would perform monitoring in accordance with the Verification Monitoring Plan, the Technology Installation and Operation Plan, and/or the Restoration Plan, all required by § 125.104(b), and any additional monitoring specified by the Director to demonstrate compliance with the applicable requirements of § 125.103(e). In developing biological monitoring conditions, the Director should consider the need for the data, and only collect data sufficient to assess the presence, abundance, life stages (including eggs, larvae, juveniles, and adults), and mortality of aquatic organisms (fish and shellfish or other organisms required to be monitored by the Director) impinged or entrained during operation of the cooling water intake structure. This type of data may be used to develop permit conditions to implement the requirements of this rule. The Director should ensure, where appropriate, that any required monitoring will allow for the detection of any annual, seasonal, and diel variations in the species and numbers of individuals that are impinged or entrained.

The Director may modify the monitoring program based on changes in physical, chemical, or biological conditions in the vicinity of the cooling water intake structure. The Director may also require monitoring of operational parameters for facilities that employ a Technology Installation and Operation Plan or Restoration Plan to comply with the requirements of § 125.103. The Director would be required to specify what monitoring or other data is to be included in a status report every two years.

4. How Would Compliance Be Determined?

This proposed rule would be implemented by the Director placing conditions consistent with the requirements of this part in NPDES permits. The application information, including components of the Comprehensive Demonstration Study, as appropriate, should demonstrate that the facility is already meeting the performance standards, or that it will install and properly operate and maintain design and construction technologies, operational measures, and/or restoration measures to meet the performance standards, or that a site-specific determination of best technology available is necessary. To support this demonstration, the facility should submit the following information to the Director:

- Data submitted with the NPDES permit application to show that the facility meets location, design, construction, and capacity requirements consistent with the compliance alternative selected;
- Data to demonstrate that the facility is meeting the performance standards or requirements consistent with the compliance alternative selected; and
- Compliance monitoring data and records as prescribed by the Director.

Facilities complying using compliance alternatives in § 125.103 (a)(2)–(5) would be required to submit a Technology Installation and Operation Plan and Verification Monitoring Plan (or Restoration Plan, which includes comparable information), regardless of how the facility wants to measure compliance. The specifics of how success in meeting the performance standards may be measured (*i.e*, the number of species, whether critical species or all species) and the method of measurement (*e.g.*, total biomass, total counts, etc.) would be determined by the Director based on review of the proposed methodology submitted by the facility in its Verification Monitoring Plan and/or Restoration Plan, and any other methods the Director considers appropriate.

The facility may request that compliance be determined based on whether it has complied with the construction, operational, maintenance, monitoring, and adaptive management requirements of its Technology Installation and Operation Plan (for design and construction technologies and/or operational measures) or Restoration Plan (for restoration measures). In this case, the facility would still assess success in meeting applicable performance standards or restoration requirements but this assessment serves to guide the adaptive management process rather than as a basis for determining compliance. After the first permit term following promulgation of this rule, facilities are only eligible for this compliance determination alternative if they have been in compliance with the terms of their Technology Installation and Operation Plan and/or Restoration Plan during the preceding permit term.

Under this compliance determination alternative, the Technology Installation and Operation Plan or Restoration Plan would specify construction, operational, maintenance, monitoring, and adaptive management requirements that can reasonably be expected to achieve success in meeting the applicable performance standards, restoration

requirements and/or site-specific requirements. These construction, operational, maintenance, monitoring, and adaptive management requirements would also be approved by the Director, who would be required to specify what verification monitoring, monitoring data and other information would be included in the facility's biennial status report.

The required elements of the Technology Installation and Operation Plan include: (1) A schedule for installation and maintenance of any new technologies; (2) operational parameters to be monitored; (3) activities to ensure the efficacy of technologies and measures; (4) a schedule and methodology for assessing the efficacy of installed technologies and measures in meeting the performance standards; (5) an adaptive management plan; and (6) for facilities using an approved compliance technology, documentation that they meet the conditions for its use. The Restoration Plan requires corresponding information as appropriate for restoration measures.

EPA believes that it is important for facilities to consider and document each of the components of the Technology Installation and Operation Plan, regardless of which compliance determination approach is used. However, the level of detail appropriate for some of the components may be different for the two different approaches. For facilities that comply by demonstrating success in meeting performance standards, particularly in cases where they are already meeting the standards and no significant changes in technologies or operations are needed, brief summaries may be sufficient for most components, though they would still need detailed documentation of their schedule and methodology for assessing efficacy of installed technologies and measures for meeting the standards. Conversely, for facilities where compliance is determined based on whether they have complied with the construction, operation, maintenance, monitoring, and adaptive management approaches required in the Technology Installation and Operation Plan or Restoration Plan, a fairly detailed specification of these requirements would be appropriate. The Director should ensure that the level of detail in the Technology Installation and Operation Plan or Restoration Plan is sufficient to support whichever compliance determination approach is selected.

Section 125.106 requires existing facilities to keep records and report monitoring data and other information specified by the Director in a biennial status report, although Directors may require more frequent reports. Facilities would also keep records of all data used to complete the permit application and show compliance with the requirements of § 125.103, any supplemental information developed under § 125.104, and any compliance monitoring data submitted under § 125.105, for a period of at least three (3) years from date of permit issuance. The Director may require that these records be kept for a longer period.

5. Alternative Site-Specific Requirements

Under § 125.103(a)(5), an existing facility may demonstrate to the Director that it has selected, installed, and is properly operating and maintaining, or will install and properly operate and maintain, design and construction technologies, operational measures, and/or restoration measures that the Director determines to be the best technology available to minimize adverse environmental impact for the facility based on the cost-cost test specified in § 125.103(a)(5)(i) or the cost-benefit test specified in § 125.103(a)(5)(ii) of the proposed rule.

Section 125.103(a)(5)(i) provides that an existing facility may demonstrate that the costs of compliance under the compliance alternatives in § 125.103(a)(3) and (4) of the rule would be significantly greater than the costs considered by the Administrator for a like facility in establishing the applicable performance standards. In such cases, the Director would make a site-specific determination of the best technology available for minimizing adverse environmental impact. The Director would establish site-specific alternative requirements based on new and/or existing design and construction technologies, operational measures, and/or restoration measures that achieve an efficacy that is, in the judgment of the Director, as close as practicable to the applicable performance standards in § 125.103(b) of the rule without resulting in significantly greater costs than those considered by the Administrator for a like facility. Section 125.103(a)(5)(ii) provides that an existing facility may demonstrate that the costs of compliance under alternatives in § 125.103(a)(3) and (4) of the rule would be significantly greater than the benefits of complying with the applicable performance standards at that facility. In such cases, the Director would make a site-specific determination of best technology available for minimizing adverse environmental impact. The Director would establish site-specific alternative requirements based on new and/or existing design and construction technologies, operational measures, and/or restoration measures that achieve an efficacy that, in the judgment of the Director, is as close as practicable to the applicable performance standards in § 125.103(b) of the rule without resulting in costs significantly greater than the benefits of meeting the performance standards.

Facility's Costs Significantly Greater Than Costs Considered by EPA

If the Director determines that data specific to the facility indicate that the costs of compliance under § 125.103(a)(3) and (4) would be significantly greater than the costs considered by the Administrator for a like facility in establishing the applicable performance standards in § 125.103(b), a facility may request a site-specific determination of best technology available for minimizing adverse environmental impacts. A facility requesting this determination would submit a Comprehensive Cost Evaluation Study and a Site Specific Technology Plan (§ 125.104(b)). The Comprehensive Cost Evaluation Study would include: engineering cost estimates in sufficient detail to document the costs of implementing design and construction technologies, operational measures, and/or restoration measures at the facility that would be needed to meet the applicable performance standards of § 125.103(b); a demonstration that the documented costs significantly exceed the costs considered by EPA for a like facility in establishing the applicable performance standards; and engineering cost estimates in sufficient detail to document the costs of implementing alternative design and construction technologies, operational measures, and/or restoration measures in the facility's Site-Specific Technology Plan developed in accordance with § 125.104(b).

To make the demonstration that compliance costs are significantly greater than those considered by EPA, the facility would first determine its actual compliance costs. To do this, the facility first should determine the costs for any new design and construction technologies, operational measures, and/or restoration measures that would be needed to meet the applicable performance standards in § 125.103(b), which may include the following cost categories: the installed capital cost of the technologies or measures; the net operation and maintenance (O&M) costs for the technologies or measures (that is,

the O&M costs for the final suite of technologies and measures once all new technologies and measures have been installed less the O&M costs of any existing technologies and measures); the net revenue losses (lost revenues minus saved variable costs) associated with net construction downtime (actual construction downtime minus that portion which would have been needed anyway for repair, overhaul or maintenance); and any pilot study costs associated with on-site verification and/or optimization of the technologies or measures. Costs should be annualized using a 7 percent discount rate, with an amortization period of 10 years for capital costs and 30 years for pilot study costs and construction downtime net revenue losses. Annualized costs should be converted to 2002 dollars ($2002), using the engineering news record construction cost index (*see Engineering News-Record*. New York: McGraw Hill). The annual average index value is 6538 for year 2002). Costs for permitting and post-construction monitoring should not be included in this estimate, as these are not included in the EPA-estimated costs against which they would be compared, as described below. Because existing facilities already incur monitoring and permitting costs and will continue to do so regardless of the compliance option selected, and these are largely independent of the specific performance standards adopted and technologies selected to meet them, EPA believes it is both simpler and more appropriate to conduct the cost comparison required in this provision using direct compliance costs (capital, net O&M, net construction downtime, and pilot study) only. Adding permitting and monitoring costs to both sides of the comparison would complicate the analysis without substantially changing the results.

To facilitate the comparison of the facility-derived costs with those considered by the Agency in establishing the proposed requirements, EPA has developed an automated cost estimating tool. This cost test tool estimates the costs using all of the same assumptions that EPA considered in developing costs for the proposed rule and would be made available to both the facility and the permitting authority. In fact, EPA used this same algorithm to estimate the incremental cost impact for this proposed rulemaking. This approach differs from the approach used in the Phase II regulations; however, EPA believes that this will provide an easier, more exact methodology for estimating those costs. In particular, EPA believes that this tool is appropriate because of the type of data on each facility that was available for this rulemaking. EPA surveyed only a segment of the Phase III universe and, therefore had data on a limited number of facilities, which required EPA to extrapolate costs for the universe of facilities potentially covered by this proposed rule. EPA therefore used a model facility approach in costing manufacturing facilities, which is the same methodology that is used in the development of most of EPA's technology-based effluent guidelines. This does not allow for providing a table that would give EPA's cost estimates for every Phase III existing facility as was done for Phase II. EPA requests comments on the use of this Cost Test Algorithm and has provided a version for review in DCN 7–0004. For more details on the cost-test algorithm, see the cost-test tool in section VIII and the Technical Development Document.

Facilities requesting site-specific performance requirements would be required to submit a Site-Specific Technology Plan. This plan is developed based on the results of the Comprehensive Cost Evaluation Study and would be required to contain the following information:

- A narrative description of the design and operation of all existing and proposed design and construction technologies, operational measures, and/or restoration measures selected in accordance with § 125.103(a)(5);
- An engineering estimate of the efficacy of the proposed and/or implemented design and construction technologies or operational measures, and/or restoration measures. This estimate would include a site-specific evaluation of the suitability of the technologies or operational measures for reducing impingement mortality and/or entrainment (as applicable) of all life stages of fish and shellfish based on representative studies (*e.g.*, studies that have been conducted at cooling water intake structures located in the same waterbody type with similar biological characteristics) and, if applicable, site-specific technology prototype or pilot studies. If restoration measures will be used, a Restoration Plan that includes the elements described in § 125.104(b) would be provided;
- A demonstration that the proposed and/or implemented design and construction technologies, operational measures, and/or restoration measures achieve an efficacy that is as close as practicable to the applicable performance standards of § 125.103(b) without resulting in costs significantly greater than either the costs considered by the Administrator for a facility like yours in establishing the applicable performance standards, or, if employing the cost-benefit test described in B below, the benefits of complying with the applicable performance standards at your facility; and,
- Design and engineering calculations, drawings, and estimates prepared by a qualified professional to support the elements of the Plan.

Facility's Costs Significantly Greater Than the Benefits of Complying With Performance Standards

A facility demonstrating that its costs are significantly greater than the benefits of complying with performance standards would produce and submit a Comprehensive Cost Evaluation Study, a Benefits Valuation Study, and a Site-Specific Technology Plan.

The Comprehensive Cost Evaluation Study is discussed in the previous section. It would require the same information for a cost-benefit site-specific determination as for a cost-cost site-specific determination, except that the demonstration in § 125.104(b) would show that the facility's actual compliance costs significantly exceed the benefits of meeting the applicable performance standards at the facility.

The Benefits Valuation Study would require that a facility use a comprehensive methodology to fully value the impacts of impingement mortality and entrainment at its site and the benefits of complying with the applicable performance standards. In addition to the valuation estimates, the benefit study would include the following:

- A description of the methodology(ies) used to value commercial, recreational, and ecological benefits (including any non-use benefits, if applicable);
- Documentation of the basis for any assumptions and quantitative estimates. If the facility plans to use an entrainment survival rate other than zero, they would submit a determination of entrainment survival at the facility based on a study approved by the Director;
- An analysis of the effects of significant sources of uncertainty on the results of the study;
- If requested by the Director, a peer review of the items submitted in the Benefits Valuation Study. The facility would be required to choose the peer reviewers in consultation with the Director who may consult with EPA and Federal, State, and Tribal fish and wildlife management agencies with responsibility for fish and wildlife potentially affected by the cooling water intake structure. Peer reviewers would be required to have appropriate

qualifications depending upon the materials to be reviewed.

• A narrative description of any non-monetized benefits that would be realized at the site if they were to meet the applicable performance standards and a qualitative assessment of their magnitude and significance.

All benefits, whether expressed qualitatively or quantitatively, should be addressed in the Benefits Valuation Study and considered by the Director in determining whether the costs of compliance would significantly exceed benefits.

The benefits assessment should begin with an impingement mortality and entrainment study, which quantifies both the baseline mortality as well as the expected change from rule compliance. The benefits assessment should include a qualitative and/or quantitative description of the benefits that would be produced by compliance with the applicable performance standards at the facility site and, to the extent feasible, monetized (dollar) estimates of all significant benefits categories using well established and generally accepted valuation methodologies. The first benefit category that would be considered is use benefits, which includes such benefits as those to commercial and recreational fishermen. Well-established revealed preference and market proxy methods exist for valuing use benefits, and these should be used in all cases where the impingement mortality and entrainment study identifies substantial impacts to harvested or other relevant species.

The second benefit category that would be considered is non-use benefits. Non-use benefits may arise from reduced impacts to ecological resources that the public considers important, such as threatened and endangered species. Non-use benefits can generally only be monetized through the use of stated preference methods. When determining whether to monetize non-use benefits, permittees and permit writers should consider the magnitude and character of the ecological impacts implied by the results of the impingement mortality and entrainment study and any other relevant information.

• In cases where an impingement mortality and entrainment characterization study identifies substantial harm to a threatened or endangered species, to the sustainability of populations of important species of fish, shellfish or wildlife, or to the maintenance of community structure and function in a facility's waterbody or watershed, non-use benefits should be monetized.[41]

• In cases where an impingement mortality and entrainment characterization study does not identify substantial harm to a threatened or endangered species, to the sustainability of populations of important species of fish, shellfish or wildlife, or to the maintenance of community structure and function in a facility's waterbody or watershed, monetization is not necessary.

Permittees should consult with their permitting authority regarding their plans for assessing ecological and non-use benefits, including whether they plan to conduct a stated preference study and if so, the basic design of the study, including such items as target population, sampling strategy, approximate sample size, general survey design, and other relevant information. When conducting quantitative benefits assessments, permittees should carefully review and follow accepted best practices for such studies. A discussion of best practices regarding valuation can be found in EPA's Guidelines for Preparing Economic Analyses (EPA 2000, EPA 240–R–00–003, September 2000) and OMB Circular A–4: Regulatory Analysis (September 17, 2003, *http://www.whitehouse.gov/omb/inforeg/circular_a4.pdf*). In the benefits assessment, permittees should present the results, as well as clearly describe the methods used, the assumptions made, and the associated uncertainties.

It is recommended that the permittee and Director seek peer review of the major biological and economic aspects of the final benefits assessment. The goal of the peer review process is to ensure that scientific and technical work products receive appropriate levels of critical scrutiny from independent scientific and technical experts as part of the overall decision-making process. In designing and implementing peer reviews, permittees and permit writers could look to EPA's Science Policy Council Handbook—Peer Review (EPA 100–B–98–00, January 1998, *http://www.epa.gov/osa/spc/index.htm*) for guidance.

The Site Specific Technology Plan, as described in the previous section, would require the same information for a cost-benefit site-specific determination as for a cost-cost site-specific determination, except that the demonstration in § 125.104(b) would show that the proposed and/or implemented technologies and measures achieve an efficacy that is as close as practicable to the applicable performance standards without resulting in costs significantly greater than the benefits of complying with the applicable performance standards at your facility.

[41] In cases where harm cannot be clearly explained to the public, monetization is not feasible because stated preference methods are not reliable when the environmental improvement being valued cannot be characterized in a meaningful way for survey respondents.

D. New Offshore Oil and Gas Extraction Facilities

Under today's proposed rule, new offshore oil and gas extraction facilities would be required to submit the application requirements consistent with § 122.21(r)(2), (3), and (4) and § 125.136 of Subpart N if they are fixed facilities and choose to comply with the Track I or II requirements in § 125.134(b) or (c). A fixed facility is defined as a bottom founded offshore oil and gas extraction facility permanently attached to the seabed or subsoil of the outer continental shelf (*e.g.*, platforms, guyed towers, articulated gravity platforms) or a buoyant facility securely and substantially moored so that it cannot be moved without a special effort (*e.g.*, tension leg platforms, permanently moored semi-submersibles) and which is not intended to be moved during the production life of the well. This definition does not include mobile offshore drilling units (MODUs) (*e.g.*, drill ships, temporarily moored semi-submersibles, jack-ups, submersibles, tender-assisted rigs, and drill barges). The Track I and Track II requirements are generally consistent with the Phase I requirements for new facilities (66 FR 65256). Under Track I, this includes source water baseline biological characterization data, velocity information, source waterbody flow information, and a design and construction technology plan. Track II requirements include source waterbody flow information and Track II comprehensive demonstration study (including source water biological study, evaluation of potential cooling water intake structure effects, and verification monitoring plan). These requirements are detailed later in this section.

As described in § 125.135, fixed facilities would also have the opportunity to conduct a cost-to-cost test and provide data to determine if compliance with the Subpart N requirements would result in compliance costs wholly out of proportion to those EPA considered in establishing the requirement, or would result in significant adverse impacts on local water resources other than

impingement or entrainment, or significant adverse impacts on energy markets. In this case, alternative requirements may be imposed in the permit. See the Phase I final preamble for a more detailed explanation of this cost-cost test which is different than the cost-cost test for existing sources (66 FR 65256).

Fixed facilities with seachests and all non-fixed (or ''mobile'') facilities would not be required to comply with standards for entrainment. Fixed facilities with seachests may choose either Track I or Track II to comply with impingement mortality performance standards. Non-fixed facilities must comply with the 0.5 feet per second through-screen design intake flow velocity performance standard for impingement mortality of Track I. In addition, the Director may determine additional design and construction technologies to minimize impingement mortality are necessary where there are either protected species of concern within the hydrologic zone of influence of the cooling water intake structure, or based on other information from fishery management services or agencies. The new mobile facility, when applying to operate under a general permit, would identify where it expects to be operating. The Director consults with the fishery management agencies, considers their data as well as any other relevant data, and decides whether to propose additional requirements based on any concerns the Director identifies (*see* § 125.134(b)(4)). For example, Region 10 has established a general permit for Cooks Inlet that established a 0.1 feet per second through-screen design intake flow velocity performance standard. However, non-fixed facilities would not be required to submit the source water baseline biological characterization data and some aspects of the source water physical data requirements. Requirements for non-fixed facilities are described later in this section.

EPA notes that some mobile facilities (*e.g.* some jack-ups) may not have seachests and therefore could feasibly install entrainment controls. EPA proposes not to require entrainment controls for these mobile facilities due to the transient nature of their operations and an expectation that they are not likely to cause significant impacts. EPA took a similar approach in its Phase II rule when the Agency did not require entrainment controls at power plants that operate less than 15 percent of the year. EPA solicits comment and data on its proposal to only require impingement controls at mobile facilities that do not have seachests.

1. For New Offshore Oil and Gas Extraction Fixed Facilities, What Information Is Required To Be Collected for the NPDES Application?

Source Water Baseline Biological Characterization Data (§ 122.21(r)(4)) (Both Track I and II)

Under today's proposed rule, new offshore oil and gas extraction fixed facilities would be required to submit source water baseline biological characterization data as required under Phase I. The data would be used to characterize the biological community in the vicinity of the cooling water intake structure and to characterize the operation of the cooling water intake structure. The data would include existing data (if available) supplemented with new field studies as necessary. Detailed data requirements are at § 122.21(r)(4). Under today's proposed rule, a group of fixed facilities may choose to conduct a regional study to collect this information as approved by the Director. EPA recognizes that many offshore oil and gas extraction facilities are regulated under NPDES general permits and that regional studies are typically conducted as part of the general permit requirements. EPA anticipates the regional studies would be conducted once each permit cycle. Under today's proposed rule, the regional study would also include annual monitoring requirements.

Velocity Information (Track I)

Today's proposed rule would require that new offshore oil and gas extraction fixed facilities submit velocity information consistent with § 125.136(b)(2). The information would be used to demonstrate to the Director that the facility is complying with the requirement to meet a maximum through-screen design intake velocity of no more than 0.5 feet per second at the cooling water intake structure. The following information would be required to be submitted: (1) A narrative description of the design, structure, equipment, and operation used to meet the velocity requirement; and (2) design calculations showing that the velocity requirement would be met at minimum ambient source water surface elevations (based on best professional judgment using available hydrological data) and maximum head loss across the screens or other device or, if the facility uses devices other than a surface intake screen, at the point of entry to the device.

Source Waterbody Flow Information (Track I and II)

Today's proposed rule would also require that new offshore oil and gas extraction fixed facilities submit source waterbody flow information in accordance with § 125.136(b)(2) or (c)(1). The information would be used to demonstrate to the Director that the facility's cooling water intake structure meets the proportional flow requirements at § 125.134(b)(3) or (c)(2). These requirements would include specific provisions for fixed facilities located on estuaries or tidal rivers to provide greater protection for these sensitive waters. Specifically, the proposed rule would require that the total design intake flow over one tidal cycle of ebb and flow must be no greater than one (1) percent of the volume of the water column within the area centered about the opening of the intake with a diameter defined by the distance of one tidal excursion at the mean low water level. Calculations and guidance on determining the tidal excursion is found in the preamble to the final Phase I rule at section VII.B.1.d.

Design and Construction Technology Plan (Track I)

Today's proposed rule would also require that new offshore oil and gas extraction fixed facilities submit a design and construction technology plan consistent with Subpart N requirements at § 125.136(b)(3). The design and construction technology plan would demonstrate that the facility has selected and will implement the design and construction technologies necessary to minimize impingement mortality and/or entrainment in accordance with § 125.134(b)(4) and/or (5). The design and construction technology plan would require delineation of the hydrologic zone of influence for the cooling water intake structure; a description of the technologies implemented (or to be implemented) at the facility; the basis for the selection of that technology; the expected performance of the technology, and design calculations, drawings and estimates to support the technology description and performance. The Agency recognizes that the selection of a specific technology or a group of technologies would depend on the individual facility and waterbody conditions.

Track II Comprehensive Demonstration Study (Track II)

If a fixed facility chooses to comply under the Track II approach, the facility would perform and submit the results of

a Comprehensive Demonstration Study (Study). This information would be used to characterize the source water baseline in the vicinity of the cooling water intake structure(s); characterize operation of the cooling water intake(s); and to confirm that the technology(ies) proposed and/or implemented at the cooling water intake structure reduce the impacts to fish and shellfish to levels comparable to those the facility would achieve were it to implement the applicable requirements in § 125.134(b)(2) and, for facilities without seachests, § 125.134(b)(5). To meet the ''comparable level'' requirement, the facility would demonstrate that it has reduced both impingement mortality and entrainment of all life stages of fish and shellfish to 90 percent or greater of the reduction that would be achieved through the applicable requirements in § 125.134(b)(2) and, for facilities without seachests, § 125.134(b)(5).

Similar to the Proposal for Information Collection required in Phase II, the facility would develop and submit a plan to the Director containing a proposal for how information will be collected to support the study. The plan would include:

- A description of the proposed and/or implemented technology(ies) to be evaluated in the Study;
- A list and description of any historical studies characterizing the physical and biological conditions in the vicinity of the proposed or actual intakes and their relevancy to the proposed Study. If the facility proposes to rely on existing source waterbody data, the data must be no more than 5 years old, and the facility would demonstrate that the existing data are sufficient to develop a scientifically valid estimate of potential impingement mortality and entrainment impacts, and provide documentation showing that the data were collected using appropriate quality assurance/quality control procedures;
- Any public participation or consultation with Federal or State agencies undertaken in developing the plan; and
- A sampling plan for data that will be collected using actual field studies in the source waterbody. The sampling plan would document all methods and quality assurance procedures for sampling, and data analysis. The sampling and data analysis methods proposed would be appropriate for a quantitative survey and based on consideration of methods used in other studies performed in the source waterbody. The sampling plan would include a description of the study area (including the area of influence of the cooling water intake structure and at least 100 meters beyond); taxonomic identification of the sampled or evaluated biological assemblages (including all life stages of fish and shellfish); and sampling and data analysis methods.

The facility would submit documentation of the results of the Study to the Director. Documentation of the results of the Study would include: Source Water Biological Study, an evaluation of potential cooling water intake structure effects, and a verification monitoring plan as described below.

Source Water Biological Study. The Source Water Biological Study would include:

(1) A taxonomic identification and characterization of aquatic biological resources including: A summary of historical and contemporary aquatic biological resources; determination and description of the target populations of concern (those species of fish and shellfish and all life stages that are most susceptible to impingement and entrainment); and a description of the abundance and temporal/spatial characterization of the target populations based on the collection of multiple years of data to capture the seasonal and daily activities (*e.g.*, spawning, feeding and water column migration) of all life stages of fish and shellfish found in the vicinity of the cooling water intake structure;

(2) An identification of all threatened or endangered species that might be susceptible to impingement and entrainment by the proposed cooling water intake structure(s); and

(3) A description of additional chemical, water quality, and other anthropogenic stresses on the source waterbody.

Evaluation of potential cooling water intake structure effects. This evaluation would include:

(1) Calculations of the reduction in impingement mortality and, if applicable, entrainment of all life stages of fish and shellfish that would need to be achieved by the technologies selected to implement to meet requirements under Track II. To do this, the facility would determine the reduction in impingement mortality and entrainment that would be achieved by implementing the requirements of § 125.134(b)(2) and, for facilities without seachests, § 125.134(b)(5).

(2) An engineering estimate of efficacy for the proposed and/or implemented technologies used to minimize impingement mortality and, if applicable, entrainment of all life stages of fish and shellfish and maximize survival of impinged life stages of fish and shellfish. The facility would demonstrate that the technologies reduce impingement mortality and, if applicable, entrainment of all life stages of fish and shellfish to a comparable level to that which would be achieved if the facility were to implement the requirements in § 125.134(b)(2) and, for facilities without seachests, § 125.134(b)(5). The efficacy projection would include a site-specific evaluation of technology(ies) suitability for reducing impingement mortality and entrainment based on the results of the Source Water Biological Study. Efficacy estimates may be determined based on case studies that have been conducted in the vicinity of the cooling water intake structure and/or site-specific technology prototype studies.

Verification monitoring plan. The fixed facility would include in the Study a plan to conduct, at a minimum, two years of monitoring to verify the full-scale performance of the proposed or implemented technologies, and/or operational measures. The verification study would begin at the start of operations of the cooling water intake structure and continue for a sufficient period of time to demonstrate that the facility is reducing the level of impingement mortality and entrainment to the level documented under the evaluation of potential cooling water intake structure effects. The plan would describe the frequency of monitoring and the parameters to be monitored. The Director would use the verification monitoring to confirm that the facility is meeting the level of impingement mortality and entrainment reduction required in § 125.134(c), and that the operation of the technology has been optimized.

2. As an Owner or Operator of a New Offshore Oil and Gas Extraction Fixed Facility, What Monitoring Is Required?

Monitoring requirements for new offshore oil and gas extraction fixed facilities include impingement mortality and entrainment if the facility does not have a seachest. If the fixed facility has a seachest, monitoring requirements include impingement mortality only.

Under today's proposal, monitoring would characterize the impingement and, if applicable, entrainment rates of commercial, recreational, and forage base fish and shellfish species identified in either the Source Water Baseline Biological Characterization data required by 40 CFR 122.21(r)(3) or the Comprehensive Demonstration Study required by § 125.136(c)(2), depending on whether the facility has a seachest.

The monitoring methods used would be consistent with those used for the Source Water Baseline Biological Characterization data required in 40 CFR 122.21(r)(4) or the Comprehensive Demonstration Study required by § 125.136(c)(2).

The fixed facility would be required to follow the monitoring frequencies identified below for at least two (2) years after the initial permit issuance. After that time, the Director may approve a request for less frequent sampling in the remaining years of the permit term and when the permit is reissued, if supporting data show that less frequent monitoring would still allow for the detection of any seasonal and daily variations in the species and numbers of individuals that are impinged or entrained.

Impingement sampling. The facility would collect samples to monitor impingement rates (simple enumeration) for each species over a 24-hour period and no less than once per month when the cooling water intake structure is in operation.

Entrainment sampling. If the fixed facility does not use a seachest, it would collect samples to monitor entrainment rates (simple enumeration) for each species over a 24-hour period and no less than biweekly during the primary period of reproduction, larval recruitment, and peak abundance identified during the Source Water Baseline Biological Characterization required by 40 CFR 122.21(r)(4) or the Comprehensive Demonstration Study required in § 125.136(c)(2). Samples would be collected only when the cooling water intake structure is in operation.

Velocity monitoring. If the facility uses a surface intake screen system, it would be required to monitor head loss across the screens and correlate the measured value with the design intake velocity. The head loss across the intake screen would be measured at the minimum ambient source water surface elevation (using best professional judgment based on available hydrological data). The maximum head loss across the screen for each cooling water intake structure would be used to determine compliance with the velocity requirement in § 125.134(b)(2). If the facility uses devices other than surface intake screens, it would monitor velocity at the point of entry through the device. Head loss or velocity would be monitored during initial facility startup, and thereafter, at the frequency specified in the NPDES permit, but no less than once per quarter.

Visual or remote inspections. The facility would conduct visual inspections or employ remote monitoring devices during the period the cooling water intake structure is in operation. Visual inspections would be conducted at least weekly to ensure that any design and construction technologies required in § 125.134(b)(4), (b)(5), (c), and/or (d) are maintained and operated to ensure that they will continue to function as designed. Alternatively, the facility would be required to inspect via remote monitoring devices to ensure that the impingement and entrainment technologies are functioning as designed.

3. What Recordkeeping and Reporting Is Required for New Offshore Oil and Gas Extraction Fixed Facilities?

Owners and operators of new offshore oil and gas extraction fixed facilities would be required to keep records of all the data used to complete the permit application and show compliance with the requirements, any supplemental information developed under § 125.136, and any compliance monitoring data submitted under § 125.137, for a period of at least three years from the date of permit issuance. The Director may require that these records be kept for a longer period.

Additionally, today's proposal would require that new offshore oil and gas extraction fixed facilities submit the following in a yearly status report:

- Biological monitoring records for each cooling water intake structure as required by § 125.137(a);
- Velocity and head loss monitoring records for each cooling water intake structure as required by § 125.137(b); and
- Records of visual or remote inspections as required in § 125.137(c).

4. For New Non-Fixed (Mobile) Offshore Oil and Gas Extraction Facilities, What Information Is Required To Be Collected for the NPDES Application?

Velocity Information (Track I)

Today's proposed rule would require that new nonfixed (mobile) offshore oil and gas extraction facilities submit velocity information consistent with § 125.136(b)(1). The information would be used to demonstrate to the Director that the facility is complying with the requirement to meet a maximum through-screen design intake velocity of no more than 0.5 feet per second at the cooling water intake structure. The following information would be required to be submitted: (1) A narrative description of the design, structure, equipment, and operation used to meet the velocity requirement; and (2) design calculations showing that the velocity requirement would be met at minimum ambient source water surface elevations (based on best professional judgment using available hydrological data) and maximum head loss across the screens or other device.

Design and Construction Technology Plan (Track I)

Today's proposed rule would require that new nonfixed (mobile) offshore oil and gas extraction facilities submit a design and construction technology plan only when required by the Director consistent with § 125.134(b)(4). The design and construction technology plan would demonstrate that the facility has selected and will implement the design and construction technologies necessary to minimize impingement mortality in accordance with § 125.134(b)(4). The design and construction technology plan would require delineation of the hydrologic zone of influence for the cooling water intake structure; a description of the technologies implemented (or to be implemented) at the facility; the basis for the selection of that technology; the expected performance of the technology, and design calculations, drawings and estimates to support the technology description and performance. The Agency recognizes that the selection of a specific technology or a group of technologies would depend on the individual facility and waterbody conditions.

5. As an Owner or Operator of a New Non-Fixed (Mobile) Offshore Oil and Gas Extraction Facility, What Monitoring Is Required?

Under today's proposal, the Director may require monitoring to characterize the impingement of commercial, recreational, and forage base fish and shellfish species as specified by the Director in accordance with § 125.134(b)(4) or § 125.134(d).

Velocity monitoring. If the mobile facility uses a surface intake screen system, it would be required to monitor head loss across the screens and correlate the measured value with the design intake velocity. The head loss across the intake screen would be measured at the minimum ambient source water surface elevation (using best professional judgment based on available hydrological data). The maximum head loss across the screen for each cooling water intake structure would be used to determine compliance with the velocity requirement in § 125.134(b)(2). If the facility uses devices other than surface intake screens, it would monitor velocity at the

point of entry through the device. Head loss or velocity would be monitored during initial facility startup, and thereafter, at the frequency specified in the NPDES permit, but no less than once per quarter.

Visual or remote inspections. The facility would conduct visual inspections or employ remote monitoring devices during the period the cooling water intake structure is in operation. Visual inspections would be conducted at least weekly to ensure that any design and construction technologies required in § 125.134(b)(4), (b)(5), (c), and/or (d) are maintained and operated to ensure that they will continue to function as designed. Alternatively, the facility would be required to inspect via remote monitoring devices to ensure that the impingement technologies are functioning as designed.

6. What Recordkeeping and Reporting Is Required for New Non-Fixed (Mobile) Offshore Oil and Gas Extraction Facilities?

Owners and operators of new mobile offshore oil and gas extraction facilities would be required to keep records of all the data used to complete the permit application and show compliance with the requirements, any supplemental information developed under § 125.136, and any compliance monitoring data submitted under § 125.137, for a period of at least three years from the date of permit issuance. The Director may require that these records be kept for a longer period.

Additionally, today's proposal would require that new mobile offshore oil and gas extraction facilities submit the following in a yearly status report:

- Velocity and head loss monitoring records for each cooling water intake structure as required by § 125.137(b); and
- Records of visual or remote inspections as required in § 125.137(c).

E. What Are the Respective Federal, State, and Tribal Roles?

Section 316(b) requirements are implemented through NPDES permits. Under 40 CFR 123.62(e), any existing approved State or Tribal section 402 permitting program would be revised to be consistent with new program requirements within one year from the date of promulgation, unless the NPDES-authorized State or Tribe amends or enacts a statute to make the required revisions. If a State or Tribe amends or enacts a statute to conform with any promulgated Phase III rule, the revision would be required to be made within two years of promulgation. States and Tribes seeking new EPA authorization to implement the NPDES program would be required to comply with the requirements when authorization is requested.

This proposed regulation would not alter State authority under section 510 of the Clean Water Act. EPA recognizes that some States have invested considerable effort in developing section 316(b) regulations and implementing programs. EPA is proposing regulations that would allow States to continue to use these programs by including in this national rule a provision that allows States to use their existing program if the State establishes that such programs would achieve comparable environmental performance. Specifically, the proposed rule would allow any State to demonstrate to the Administrator that it has adopted alternative regulatory requirements that would result in environmental performance within each relevant watershed that is comparable to the reductions in impingement mortality and entrainment that would be achieved under § 125.103.

In addition to updating their programs to be consistent with today's proposed rule, States and Tribes authorized to implement the NPDES program would be required to implement the cooling water intake structure requirements following promulgation of the proposed regulations. The requirements would have to be implemented upon the issuance or reissuance of permits containing the requirements of Subpart K or N. Duties of an authorized State or Tribe under this regulation may include:

- Review and verification of permit application materials, including a permit applicant's determination of source waterbody classification and the flow or volume of certain waterbodies at the point of the intake;
- Determination of the standards in § 125.103(b) or § 125.134 that apply to the facility, or authorize alternative requirements in § 125.135;
- Verification of a permit applicant's determination of whether it meets or exceeds the applicable performance standards or requirements;
- Verification that a permit applicant's Design and Construction Technology Plan demonstrates that the proposed alternative technologies would reduce the impacts to fish and shellfish to levels required;
- Verification that a permit applicant meets the cost test and that permit conditions developed on a site-specific basis are justified based on documented costs, and, if applicable, benefits;
- Verification that a permit applicant's proposed restoration measures would meet regulatory standards (existing facilities only);
- Development of draft and final NPDES permit conditions for the applicant implementing applicable section 316(b) requirements pursuant to this rule; and
- Ensuring compliance with permit conditions based on section 316(b) requirements.

EPA also will implement these requirements where States or Tribes are authorized to implement the NPDES program but do not have sufficient authority to implement these requirements.

In the discussion of Federal, State and Tribal roles in the preamble to the Phase II final regulations (69 FR 41643, 3rd col.), EPA stated that ''EPA will implement these requirements where States or Tribes are not authorized to implement the NPDES program. EPA also will implement these requirements where States or Tribes are authorized to implement the NPDES program but do not have sufficient authority to implement these requirements.'' EPA notes that the second sentence in this quote incorrectly stated EPA's authority. In fact, EPA does not have authority to issue NPDES permits where States or Tribes are authorized to administer the NPDES program except after EPA vetoes a permit. (See § 123.61(c) and § 123.44(h).) Today's preamble correctly states that States and Tribes authorized to implement the NPDES program would need to have or obtain sufficient authority to implement final Phase III regulations. EPA intends to issue guidance to clarify that, pursuant to § 123.25(a)(36), States and Tribes authorized to implement the NPDES program must have or obtain sufficient authority to implement the Phase II regulations.

F. Are Permits for Phase III Facilities Subject to Requirements Under Other Federal Statutes?

EPA's NPDES permitting regulations at 40 CFR 122.49 contain a list of Federal laws that might apply to Federally issued NPDES permits. These include the Wild and Scenic Rivers Act, 16 U.S.C. 1273 *et seq.*; the National Historic Preservation Act of 1966, 16 U.S.C. 470 *et seq.*; the Endangered Species Act, 16 U.S.C. 1531 *et seq.*; the Coastal Zone Management Act, 16 U.S.C. 1451 *et seq.*; and the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.* See 40 CFR 122.49 for a brief description of each of these laws. In addition, the provisions of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.*, relating to essential

fish habitat might be relevant. Nothing in this proposed rulemaking would authorize activities that are not in compliance with these or other applicable Federal laws.

VIII. Economic Impact Analysis

The discussion in this section summarizes EPA's analysis of total social cost and economic impacts for three co-proposed options for existing facilities: the ''50 MGD for All Waterbodies'' option, the ''200 MGD for All Waterbodies'' option, and the ''100 MGD for Certain Waterbodies'' option. These options are described more fully in section VI. EPA also conducted analyses for other potential regulatory definitions, including applying requirements to all facilities with design intake flow of at least 2 MGD. This definition would have included all 683 potentially regulated Phase III facilities. This and other potential regulatory specifications are not being proposed because of economic practicability concerns, but analyses for them can be found in *''Economic Analysis for the Proposed Section 316(b) Rule for Phase III Facilities''* (hereafter referred to as the ''EA''; DCN 7–0002). This section also presents EPA's estimates of total social cost and economic impacts for new offshore oil and gas extraction facilities. EPA's assessment of costs and economic impacts, including results for all analyzed regulatory definitions, can be found in the EA.

A. Existing Phase III Facilities: Manufacturers and Electric Power Producers

1. Overview of Affected Industry Sectors

For the economic analyses, EPA distinguished between the types of facilities as follows:

- Manufacturing and Other Industries (''Manufacturers'')—facilities in the paper, aluminum, steel, chemicals, petroleum and other industries. In addition to engaging in production activities, some of these facilities also generate electricity for their own use and occasionally for sale.
- Electric power producers (''Electric Generators'')—facilities owned by investor-owned utilities, municipalities, States, Federal authorities, cooperatives, and non-utilities.

Within the Manufacturers group, EPA focused its analysis on five manufacturing industries—Paper, Chemicals, Petroleum, Aluminum, and Steel (the ''Primary Manufacturing Industries'')—as the industries using the largest amounts of cooling water outside of the electric power generating industry. EPA's economic analysis for these industries is based on a statistically-valid survey sample of facilities in these five industries. This analysis also considers the effect of the regulation on facilities in other industries (''Other Industries'') that use cooling water to a lesser extent than the five Primary Manufacturing Industries and that are also covered by the proposal. The analysis for Other Industries is restricted to a limited sample of facilities for which EPA received detailed surveys but which are not part of the statistically valid sample. As a result, EPA's analysis of facilities in the Other Industries group is limited to the known facilities in this group. EPA has not specifically estimated the total number of facilities in the Other Industries group that may be subject to the regulation because EPA does not believe that this number can be reliably extrapolated from the number of known facilities in this group. However, because the six surveyed industries (including electric power) account for 99% of total cooling water withdrawals, EPA believes that few additional facilities in the Other Industries group are potentially subject to today's proposed regulation. EPA seeks comment and data on the number of facilities in the Other Industries group that may be subject to today's proposal.

EPA's analysis also reflects a limited number facilities in the Virgin Islands and Puerto Rico for which EPA received detailed survey responses. These facilities have also been included in EPA's economic analysis. EPA is clarifying today's proposal would apply to any facility meeting the applicability criteria in § 125.101. EPA seeks comment and data on the total number of facilities that may be subject to today's proposal.

EPA's review of the engineering characteristics of cooling water intake and use in the Other Industries group indicates that cooling water intake and use in these industries do not differ materially from cooling water intake and use in the Primary Manufacturing Industries and the electric power industry. In addition, EPA specifically analyzed the economic impacts of the proposed options on known facilities in the Other Industries group. EPA believes that its findings of no economic impact to the known facilities in Other Industries and the practicability of the proposed options are generally applicable to the full breadth of industries within the regulation's scope. EPA is seeking comment and data on the economic impact and practicability of the proposed options on facilities in the Other Industries group.

EPA estimates that as many as 566 facilities in the Manufacturers segment (including 537 facilities in the Primary Manufacturing Industries and 29 known facilities in Other Industries), and 117 Electric Generators are potentially subject to this rulemaking, based on a design intake flow applicability threshold of greater than 2 MGD. EPA excluded from the analysis for each option those facilities that are below the option's design intake flow applicability threshold and would therefore not incur compliance costs. In addition, EPA's analyses identified existing facilities that are in severe financial distress independent of regulation. These facilities, referred to as ''baseline closures,'' were determined as likely to terminate business operations independent of the proposed options and were also excluded from the analyses presented in this section.

Exhibit VIII–1 presents, by waterbody type and industry, EPA's estimates of (1) the number of existing facilities potentially subject to this rulemaking, (2) the number of baseline closures, and (3) the number of existing facilities subject to national requirements under five different design intake flow applicability thresholds.

EXHIBIT VIII–1.—PHASE III EXISTING FACILITY COUNTS, BY WATERBODY TYPE AND INDUSTRY

Industry	Potentially subject to regulation	Baseline closure	Facilities subject to national requirements with DIF applicability threshold of greater than or equal to (in MGD), excluding baseline closures				
			2	20	50	100	200
All Waterbodies							
Primary Man. Industries	537	73	464	290	127	58	23
Other Industries	29	4	25	12	9	5	2

EXHIBIT VIII–1.—PHASE III EXISTING FACILITY COUNTS, BY WATERBODY TYPE AND INDUSTRY—Continued

Industry	Potentially subject to regulation	Baseline closure	Facilities subject to national requirements with DIF applicability threshold of greater than or equal to (in MGD), excluding baseline closures				
			2	20	50	100	200
Electric Generators	117	3	114	51	0	0	0
Total	683	80	603	353	136	63	25
Total DIF (MGD)	40,441	4,440	36,001	33,683	26,714	21,587	16,144
Coastal and Great Lakes							
Primary Man. Industries	110	17	94	67	35	17	10
Other Industries	9	3	6	5	4	2	1
Electric Generators	11	0	11	4	0	0	0
Total	130	20	111	76	39	19	11
Total DIF (MGD)	11,010	2,423	8,587	8,179	7,190	5,747	4,418
Inland							
Primary Man. Industries	427	56	371	223	92	41	13
Other Industries	20	1	19	7	5	3	1
Electric Generators	106	3	103	47	0	0	0
Total	553	60	493	277	97	44	14
Total DIF (MGD)	29,431	2,017	27,414	25,504	19,524	15,841	11,726

2. Method for Estimating Costs to Manufacturers and Electric Generators

EPA estimated capital costs of technologies, annual operation and maintenance costs, installation downtime costs, and permitting costs. The cost estimates reflect the incremental costs attributed only to today's proposal. For example, facilities with closed-cycle recirculating systems already meet the proposed performance standards, and therefore would not incur costs for new technologies, additional annual operational costs, or downtime costs (though such facilities would still incur some components of permitting costs).

For estimating the incremental compliance costs attributable to the proposed options, EPA developed both facility-specific and model facility costs. Facility-specific compliance costs require detailed process information about many, if not all, facilities in the industry. These data typically include production, capacity, water use, wastewater generation, monitoring results, geographic location, financial conditions, technologies and practices already in place, and other facility-specific data. EPA used a detailed technical survey of Electric Generators and Manufacturers to collect these data (see section III for more information on EPA's detailed survey). These data and detailed process information were used to determine whether new controls would be necessary to meet the standards of the proposed rule, and to estimate the cost of installing any new or additional controls. While the Agency is confident that the suite of available technologies can achieve compliance with the proposed performance requirements (60–90 percent reduction in entrainment and 80–95 percent reduction in impingement mortality relative to the calculation baseline), EPA lacks sufficient data and resources to determine the precise cost and performance of each technology on a site-specific basis. Therefore, EPA first calculated the facility-specific costs for 348 facilities for which detailed information was available, and applied the model facility approach to the remaining facilities to calculate the industry-level costs for the approximately 700 existing Manufacturers and Electric Generators.

In costing each model facility, EPA, to a degree, departed from its traditional least-cost approach. The least-cost approach relies on the principle that the complying facility will choose the most cost-effective compliance alternative to meet the regulatory requirements. In most cases, this means the facility will install the least-cost technology that meets the minimum standard. Instead of selecting the least-cost compliance alternative (see section VI for a description of the compliance alternatives), a best-performing technology was assigned to a model facility utilizing a spreadsheet program called the ''cost-test tool.'' The cost-test tool determines one of two possible performance expectations: (1) Impingement requirements only or (2) both impingement and entrainment requirements. The cost-test tool then determines a compliance response for the facility/intake by accounting for existing technologies (such as wedgewire screens) and conditions (such as a shoreline intake location or the through-screen velocity). Next, the cost-test tool applies EPA's decision tree for assigning one of 12 technology modules as the best-performing technology to a site (*see* Figure 2–1 of the Phase III TDD for a schematic of this decision tree). This should not be construed to mean today's proposed options would require facilities to install the technologies selected by the cost-test tool. Under today's proposal, facilities could choose any technology, combination of technologies, or operational measures that would meet the requirements of the selected compliance alternative along with any other additional permit requirements. Finally, cost estimates are derived through a combination of calculations and functions that apply facility-specific data to the selected technology module. The cost outputs include capital costs, incremental operating and maintenance (O&M) costs, and installation downtime (in weeks).

Based on data from EPA's detailed technical survey, EPA believes that cooling water intake structures at Electric Generators are, in general, no different from those intake structures employed by Manufacturers. Therefore, the Phase II costs attributed to control technologies were used to calculate costs for potentially regulated existing Phase III Manufacturers and Electric Generators. EPA generally utilized the original methodology published in the Phase II NODA (68 FR 13522; March 19, 2003), accounting for comments received from the public. EPA also used the costing equations it developed for the final Phase II rule, along with the site-specific data obtained from the detailed surveys. EPA requests comment, including supporting data, on the use of technologies and costing equations from the Phase II rule in the Phase III analysis.

Permit costs, including costs for permitting, monitoring, permit reissuance, and recordkeeping, are not included in the cost-test tool. Costs for these activities were developed separately as part of the *Information Collection Request (ICR) for Cooling Water Intake Structures Phase III Proposed Rule* (''ICR''; DCN 7–0001). The per facility permit costs were added to the incremental compliance costs, along with installation downtime costs (where appropriate), in developing the total model facility cost. The per facility permit costs may be found in Chapter B1 of the EA.

In addition to the capital and annual operating costs of the selected technology module, 16 facilities (sample-weighted, with more than 50 MGD intake, and excluding baseline closures) incur downtime costs. Downtime costs generally reflect decreased revenues due to lost production or costs of supplemental power purchases during the retrofit of existing cooling water intake structures. EPA determined that an additional four facilities with multiple intakes could shut off any one intake and still meet their average intake flow without exceeding the total design intake flow of the remaining intakes. Furthermore, these facilities all have shoreline intakes, negating the need to maintain costly offshore equipment necessary to retrofit one intake at a time. EPA assumes these four facilities could retrofit one intake at a time, thereby avoiding downtime costs. In all other cases, the length of downtime (in weeks) and the general approach to estimating the cost of downtime are the same as used for the Phase II analysis. See chapter 5 of the TDD for more details. EPA solicits comment and supporting data on this approach to estimating downtime costs.

Total social costs are presented in section VIII.C of this preamble.

Under today's proposal, facilities have five compliance alternatives for meeting the performance standards. Not all of these compliance alternatives are addressed by the cost-test tool. The cost-test tool, and therefore total national costs, do not specifically adjust for site-specific requirements developed in accordance with compliance alternative 5 (see also section VI of this preamble). While costs for facilities requesting alternative requirements based on the cost-cost test should be comparable to EPA's estimated costs, costs for facilities requesting alternative requirements based on the cost-benefit test may be less. In addition, each model facility was costed for a single best-performing technology module, which does not necessarily reflect the most cost-effective compliance alternative. Thus, although EPA's costs for each model facility to install a specified compliance technology are believed to be accurate, the total national costs of today's proposal may be overstated.

EPA solicits comment on all aspects of this costing approach.

3. Social Cost for Manufacturers and Electric Generators

EPA calculated the social cost of the three co-proposed options for existing Manufacturers and Electric Generators using two discount rate values: 3 percent and 7 percent. All dollar values presented in this preamble are in 2003 dollars (average or mid-year). For the analysis of social costs, EPA discounted all costs to the beginning of 2007, the date at which this proposal is assumed to become effective. EPA assumed that all facilities subject to the regulation would achieve compliance between 2010 and 2014, and estimated the time profile of compliance and related costs over 30 years from the year of compliance for each complying facility.[42] Costs incurred by governments for administering the regulation were analyzed over the same time frame. The last year for which costs were tallied is 2043. At a 3 percent rate, EPA estimated total annualized social costs of $47.3 million for the ''50 MGD for All Waterbodies'' option, $22.8 million for the ''200 MGD for All Waterbodies'' option, and $17.6 million for the ''100 MGD for Certain Water bodies'' option. At a 7 percent rate, these values are $50.1 million for the 50 MGD option, $24.1 million for the 200 MGD option, and $18.3 million for the 100 MGD option. The largest component of social cost is the pre-tax cost of regulatory compliance incurred by complying facilities; these costs include pilot study costs, one-time technology costs of complying with the rule, one-time costs of installation downtime, annual operating and maintenance costs, and permitting costs (initial permit costs, annual monitoring costs, and permit reissuance costs). Social cost also includes implementation costs incurred by Federal and State governments. Exhibit VIII–2 presents the social cost of the proposed options, by type of cost and type of facility, using 3 percent and 7 percent discount rates.

EXHIBIT VIII–2.—ANNUALIZED SOCIAL COST

[In millions, 2003 $]

	50 MGD all waterbodies	200 MGD all waterbodies	100 MGD certain waterbodies
3% Discount Rate			
Direct Compliance Cost:			
Primary Manufacturing Industries	$42.7	$21.7	$16.7
Other Industries	4.1	1.0	0.7
Electric Generators	0.0	0.0	0.0

[42] Benefits are tallied and discounted in the same way, although the total time profile for recognition of benefits is longer than the profile for recognition of costs.

EXHIBIT VIII–2.—ANNUALIZED SOCIAL COST—Continued

[In millions, 2003 $]

	50 MGD all waterbodies	200 MGD all waterbodies	100 MGD certain waterbodies
Total Direct Compliance Cost	46.8	22.6	17.5
State and Federal Administrative Cost	0.6	0.1	0.2
Total Social Cost	47.3	22.8	17.6
7% Discount Rate			
Direct Compliance Cost:			
Primary Manufacturing Industries	45.1	23.1	17.4
Other Industries	4.4	0.9	0.7
Electric Generators	0.0	0.0	0.0
Total Direct Compliance Cost	49.5	24.0	18.1
State and Federal Administrative Cost	0.6	0.1	0.2
Total Social Cost	50.1	24.1	18.3

As shown in Exhibit VIII–2, compliance cost in the Manufacturers segment accounts for the substantial majority of total social cost and direct compliance cost under all three options. No Electric Generators would be subject to the national requirements under any of the three co-proposed options. On a per facility basis and at a 3 percent discount rate, annualized pre-tax costs in the Manufacturers segment amount to $349,000 under the ''50 MGD for All Waterbodies'' option, $920,000 under the ''200 MGD for All Waterbodies'' option, and $929,000 under the ''100 MGD for Certain Waterbodies'' option. The corresponding values using a 7 percent discount rate are $369,000 under the ''50 MGD for All Waterbodies'' option, $974,000 under the ''200 MGD for All Waterbodies'' option, and $962,000 under the ''100 MGD for Certain Waterbodies'' option. Because the 200 MGD option and the 100 MGD option apply national categorical requirements to a smaller number of higher flow facilities than the 50 MGD option, they result in a lower total national cost but a higher cost per regulated facility. Individual facilities that are subject to the requirements of the 200 MGD option or the 100 MGD option incur the same compliance costs as under the 50 MGD option (in which they are also included); however, the average costs per regulated facility are higher under the 200 MGD and 100 MGD options because only the higher flow, and therefore higher cost, facilities incur costs under these options.

EPA's estimate of Federal and State government costs for administering this proposal is comparatively minor in relation to the estimated direct cost of regulatory compliance. EPA estimates government annual administrative costs of approximately $0.6 million (50 MGD option), $0.1 million (200 MGD option), and $0.2 million (100 MGD option) under both discount rates.

4. Economic Impacts for Manufacturers and Electric Generators

The economic impact analyses assess how facilities, and the firms that own them, are expected to be affected financially by the analyzed options. The facility impact analysis starts with compliance cost estimates (see section VIII.A.2) and then calculates how these compliance costs would affect financial performance and other economic conditions.

a. Manufacturers (Primary Manufacturing Industries and Other Industries)

This section presents EPA's estimated economic impacts on Manufacturers for the three co-proposed options. Measures of economic impact include facility closures and associated losses in employment, financial stress short of closure (''moderate impacts''), and firm-level impacts. EPA eliminated from the analysis those facilities showing materially inadequate financial performance in the baseline, that is, in the absence of the rule. EPA judges these facilities, which are referred to as baseline closures, to be at substantial risk of financial failure regardless of any additional financial burden that might result from the proposed Phase III regulation.

For the remaining facilities, EPA identified a facility as a regulatory closure if it would have operated under baseline conditions but would fall below an acceptable financial performance level under the new regulatory requirements. EPA's analysis of regulatory closures is based on the estimated change in facility after-tax cash flow (cash flow) as a result of the regulation and specifically examines whether the change in cash flow would be sufficient to cause the facility's going concern business value to become negative. EPA calculated business value using a discounted cash flow framework in which cash flow is discounted at an estimated cost of capital to calculate the going concern value of the facility. The specific definition of cash flow used in these analyses is after-tax free cash flow available to all capital—equity and debt. Correspondingly, the cost of capital reflects the combined cost, after-tax, of equity and debt capital. For its analysis of economic/financial impacts on the Manufacturers industry segment, EPA used 7 percent as a real, after-tax cost of capital.

In these analyses, EPA first calculated the baseline going concern value of the facility using its baseline cash flow—*i.e.*, facility cash flow before compliance-related outlays. For this calculation, EPA used the three-year average of cash flow as reported in each facility's survey response and adjusted to constant 2003 dollars. In addition to adjusting facility cash flow values for inflation to 2003, EPA adjusted facility baseline cash flow to reflect the estimated *real* change (*i.e.*, independent of inflation) in business performance in the manufacturing industries from the time of the facility survey, 1996–1998, to the present. EPA also estimated an ongoing outlay for replacement of the facility's capital equipment and included this as an adjustment to baseline cash flow. EPA included an allowance of ongoing capital outlays in

the calculation of cash flow because such outlays for replacement and refurbishment of capital equipment occur in the ordinary course of business and represent a cash outlay for the business. EPA estimated these outlays based on an econometric analysis of actual capital outlays over an 11-year period by businesses in the five Manufacturers industry segments. This analysis accounted for national economic conditions, business conditions in the specific industry segments, and financial performance of the individual businesses (see EA, Chapter B3 for details of this analysis and the details of the cash flow calculation). Using this adjusted baseline cash flow, if EPA found the facility's estimated going concern value to be negative, then the facility was judged a baseline closure—*i.e.*, likely to fail financially, independent of incurrence of compliance costs—and removed the facility from further consideration in the impact analysis.

As the second step in the facility impact analysis, EPA adjusted the baseline cash flow to reflect the expected financial effects of compliance technology installation and operation. For this analysis, EPA assumed that *none* of the facility's compliance costs could be passed on to its customers as price and revenue increase—*i.e.*, all compliance costs must be absorbed within the facility's cash flow. EPA then recalculated the facility's business value using the adjusted post-compliance cash flow. If this analysis found that the facility's business value would become negative as a result of meeting compliance requirements, then EPA judged the facility to be a regulatory closure.

EPA also identified facilities that would likely incur moderate financial impacts, but that are not expected to close, as a result of the proposed rule. EPA established thresholds for two measures of financial performance and condition—interest coverage ratio (ICR) and pre-tax return on assets (PTRA)—and compared the facilities' performance before and after compliance under each regulatory option with these thresholds. EPA calculated ICR as pre-tax operating cash flow—earnings before interest, taxes, and depreciation—divided by interest expense. This measure provides insight into a business' ability to service its debt on the basis of current, ongoing financial performance and to borrow for capital investments. EPA calculated PTRA as the ratio of pre-tax operating income—earnings before interest and taxes—to assets. This ratio measures the operating performance and profitability of a business' assets independent of financial structure and tax circumstances. For this analysis, EPA developed industry-specific thresholds from data compiled by Risk Management Association, Inc. (RMA). The threshold values represent the 25th percentile values of PTRA and ICR for statements received by RMA for the eight years from 1994 to 2001 within relevant industries. Thresholds by sector ranged from 1.8% to 2.9% for PTRA and from 2.0 to 2.4 for ICR (see EA Chapter B3 for additional information). EPA attributed incremental moderate impacts to the rule if both financial ratios exceeded threshold values in the baseline (*i.e.*, there were no moderate impacts in the baseline), but at least one financial ratio fell below the threshold value in the post-compliance case.

i. Baseline Closure Analysis

Exhibit VIII–3 presents projected baseline closures for the estimated facilities in the Primary Manufacturing Industries and additional known facilities in Other Industries.[43] From the analysis as outlined above, EPA determined that 76 facilities (or 14 percent) of the estimated 532 regulated facilities in the five Primary Manufacturing Industries are baseline closures. The highest percentages of baseline closures occur in the Steel industry sector (43 percent) and Aluminum industry sector (33 percent). An additional four facilities (or 18 percent) of the 22 known facilities in Other Industries are projected to be baseline closures. These facilities were excluded from the post-compliance analysis of regulatory impacts.

EXHIBIT VIII–3.—SUMMARY OF BASELINE CLOSURES FOR MANUFACTURERS

Sector	Total number of facilities	Number of baseline closures	Percentage of baseline closures	Operating in baseline
Paper	230	32	13.9	198
Chemicals	178	4	2.2	173
Petroleum	36	5	13.9	30
Steel	68	29	42.6	40
Aluminum	21	7	33.3	14
Total Facilities in Primary Manufacturing Industries	532	76	14.3	456
Additional known facilities in Other Industries	22	4	18.2	18
Total Manufacturers	554	80	14.4	474

[43] The estimated number of Manufacturers considered in the impact analysis (554) differs from the number reported in the broader analyses (566) because of the exclusion of some sample surveys with missing data and the rescaling of the remaining surveys to extrapolate national impacts. EPA determined that the survey responses of 14 sample facilities lacked certain financial data needed for the facility impact analysis while containing sufficient data to support estimates of facility counts and compliance costs. EPA therefore retained these sample facilities (37 sample weighted facilities) in the broader analyses but excluded them from the impact analysis. When these sample facilities were excluded from the impact analysis, the sample weights for the remaining facilities within the affected sample frames were adjusted upwards to account for their removal. The difference in the reported facility totals in the impact and social cost analyses reflects the removal of these 14 facilities and the use of adjusted sample weights. The removal of specific sample facilities from the analysis universe and simultaneous adjustment of sample weights to account for their removal yields the same estimate of the total combined population of Manufacturers and Electric Generators for the analysis. However, as a result of the sample stratification methodology, the estimates of the total facility populations for Manufacturers only differ slightly between the two sample facility cases. Both values are valid statistical estimates of the same, but unknown, value of the Manufacturers facility population.

ii. Number of Facilities Passing the Baseline Closure Analysis and Subject to National Categorical Requirements

As described above, the number of Manufacturers subject to national categorical requirements differs according to (1) the options' design intake flow (DIF) applicability thresholds, and (2) the type of waterbodies to which they would apply. Of the three co-proposed options presented here, the ''100 MGD for Certain Waterbodies'' option would apply to the smallest number of the facilities that passed the baseline closure analysis (''baseline-pass facilities'')—20 facilities, or 18 facilities in the Primary Manufacturing Industries and two known facilities in Other Industries (*see* Exhibit VIII–4). The ''200 MGD for All Waterbodies'' option would apply to 24 baseline-pass facilities, or 22 facilities in the Primary Manufacturing Industries and two known facilities in Other Industries. The ''50 MGD for All Waterbodies'' would apply to 133 baseline-pass facilities, or 127 facilities in the Primary Manufacturing Industries and 6 known facilities in Other Industries.

EXHIBIT VIII–4.—NUMBER OF BASELINE-PASS MANUFACTURING FACILITIES SUBJECT TO NATIONAL CATEGORICAL REQUIREMENTS BY OPTION AND SECTOR

Sector	Total operating in baseline	Number of facilities subject to national categorical requirements					
		50 MGD all waterbodies		200 MGD all waterbodies		100 MGD certain waterbodies	
		Number	Percent	Number	Percent	Number	Percent
Paper	198	37	18.7	3	1.5	0	0.0
Chemicals	173	52	30.1	5	2.9	7	4.0
Petroleum	30	13	43.3	3	10.0	5	16.7
Steel	40	22	55.0	9	22.5	6	15.0
Aluminum	14	5	35.7	1	7.1	0	0.0
Total Facilities in Primary Manufacturing Industries	456	127	27.9	22	4.8	18	3.9
Additional known facilities in Other Industries	18	6	33.3	2	11.1	2	11.1
Total Manufacturers	474	133	28.1	24	5.1	20	4.2

Note: May not sum to totals due to independent rounding.

iii. Post-Compliance Impact Analysis; Summary of Impacts

Of the 474 Manufacturers potentially subject to regulation after baseline closures, EPA estimated that no facilities would close or incur employment losses as a result of the three co-proposed options considered here. EPA also found that none of the 474 baseline-pass facilities would incur a moderate economic impact as a result of the three co-proposed options.

Exhibit VIII–5 summarizes the estimated impacts of the proposed rule on Manufacturers by option, including facility impacts and total annualized compliance costs on an after-tax basis. The reported costs include no compliance costs for facilities assessed as baseline closures. The total annualized, after-tax compliance cost reported in Exhibit VIII–5 represents the cost actually incurred by complying firms, taking into account the reductions in tax liability resulting from compliance outlays and assuming no recovery of costs from customers through increased prices. The after-tax analysis uses a combined Federal/State tax rate, and accounts for facilities' baseline tax circumstances. Specifically, tax offsets to compliance costs are limited not to exceed facility-level tax payments as reported in facility questionnaire responses. The total annualized, after-tax compliance cost reported here is the sum of annualized, after-tax costs by facility at the year of compliance, using a 7 percent after-tax cost of capital. This cost calculation differs in concept from the calculation of compliance costs as included in the calculation of the total social costs of the regulation. For the social cost calculation, which is presented in section VIII.A.2, the year-by-year stream of total pre-tax compliance costs for all facilities is discounted to the assumed effectiveness date of the 316(b) Phase III final rule—beginning of year 2007—and then annualized. Two social discount rate values, 3 percent and 7 percent, are used in the social cost analysis.

EXHIBIT VIII–5.—FACILITY IMPACTS FOR MANUFACTURERS

	50 MGD all waterbodies	200 MGD all waterbodies	100 MGD certain waterbodies
Primary Manufacturing Industries			
Number of Facilities Operating in Baseline	456	456	456
Number of Facilities Subject to National Requirements	127	22	18
Percentage of Facilities Subject to National Requirements	27.9	4.8	3.9
Number of Closures (Severe Impacts)	0	0	0
Percentage of Facilities Closing	0.0	0.0	0.0
Number of Facilities with Moderate Impacts	0	0	0
Percentage of Facilities with Moderate Impacts	0.0	0.0	0.0
Annualized Compliance Costs (after tax, million $2003)	$32.8	$13.7	$15.8

EXHIBIT VIII–5.—FACILITY IMPACTS FOR MANUFACTURERS—Continued

	50 MGD all waterbodies	200 MGD all waterbodies	100 MGD certain waterbodies
Additional Known Facilities in Other Industries			
Number of Facilities Operating in Baseline	18	18	18
Number of Facilities Subject to National Requirements	6	2	2
Percentage of Facilities Subject to National Requirements	33.3	11.1	11.1
Number of Closures (Severe Impacts)	0	0	0
Percentage of Facilities Closing	0.0	0.0	0.0
Number of Facilities with Moderate Impacts	0	0	0
Percentage of Facilities with Moderate Impacts	0.0	0.0	0.0
Annualized Compliance Costs (after tax, million $2003)	$5.2	$0.7	$0.6

iv. Firm-Level Impact

In addition to analyzing the impact of the regulation at the facility level, EPA also examined the impact of the proposed rule on firms that own manufacturing facilities with cooling water intake structures. A firm that owns multiple facilities could be adversely affected due to the cumulative burden of regulatory requirements over these facilities. EPA also used the firm-level analysis to compare impacts on small versus large firms, as required by the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act. Section XI.C of this preamble discusses RFA/SBREFA issues. For the assessment of firm-level effects, EPA calculated annualized after-tax compliance costs as a percentage of firm revenue and reports here the estimated number and percentage of affected firms incurring compliance costs in three cost-to-revenue ranges: less than 1 percent; at least 1 percent but less than 3 percent; and 3 percent or higher.

EPA's sample-based analysis of facilities in the Primary Manufacturing Industries supports specific estimates of the number of facilities expected to be affected by the regulation and the total compliance costs expected to be incurred in these facilities. However, the sample-based analysis does not support specific estimates of the number of firms that own facilities in the Primary Manufacturing Industries. In addition, and as a corollary, the sample-based analysis does not support specific estimates of the number of regulated facilities that may be owned by a single firm, or of the total of compliance costs across regulated facilities that may be owned by a single firm. For the firm-level analysis, EPA therefore considered two approximate bounding cases based on the sample weights developed from the facility survey. These cases provide a range of estimates for the number of firms incurring compliance costs and the costs incurred by any firm owning a regulated facility. The cases are as follows:

1. *Upper bound estimate of number of firms owning facilities that face requirements under the regulation; lower bound estimate of total compliance costs that a firm may incur.* For this case, EPA assumed (1) that a firm owns only the regulated sample facility(ies) that it is known to own from the sample analysis and (2) that this pattern of ownership, observed for sampled facilities and their owning firms, extends over the facility population represented by the sample facilities. This case minimizes the possibility of multi-facility ownership by a single firm and thus maximizes the count of affected firms, but also minimizes the potential cost burden to any single firm.

2. *Lower bound estimate of number of firms owning facilities that face requirements under the regulation; upper bound estimate of total compliance costs that a firm may incur.* For this case, EPA inverted the prior assumption and assumed that any firm owning a regulated sample facility(ies), owns the known sample facility(ies) and all of the sample weights associated with the sample facility(ies). This case yields an approximate lower bound estimate of the count of affected firms, and an approximate upper bound estimate of the potential cost burden to any single firm (see EA Chapter B3 for information on the analysis of firm-level impacts).

EPA included the additional known facilities in Other Industries in these analyses but since these facilities have no sample weight (*i.e.*, they are not modeled to represent facilities other than themselves), the upper and lower bound estimates were not applicable to them.

Exhibit VIII–6 summarizes the results of the firm-level analysis for these two analytic cases.

EXHIBIT VIII–6.—FIRM-LEVEL AFTER-TAX ANNUAL COMPLIANCE COSTS AS A PERCENTAGE OF REVENUE

Number of firms in the analysis	Pot. reg.	No costs		Number and percentage with after tax annual compliance costs/annual revenue of					
		Number	Percent	Less than 1%		1–3%		At Least 3%	
				Number	Percent	Number	Percent	Number	Percent
Primary Manufacturing Industries									
Case 1: Upper bound estimate of number of firms owning facilities that face requirements under the regulation; lower bound estimate of total compliance costs that a firm may incur									
50 MGD All Waterbodies	313	208	66	105	34	0	0	0	0
200 MGD All Waterbodies	313	292	93	21	7	0	0	0	0
100 MGD Certain Waterbodies	313	293	94	21	7	0	0	0	0

EXHIBIT VIII–6.—FIRM-LEVEL AFTER-TAX ANNUAL COMPLIANCE COSTS AS A PERCENTAGE OF REVENUE—Continued

Number of firms in the analysis	Pot. reg.	No costs		Number and percentage with after tax annual compliance costs/annual revenue of					
		Number	Percent	Less than 1%		1–3%		At Least 3%	
				Number	Percent	Number	Percent	Number	Percent
Case 2: Lower bound estimate of number of firms owning facilities that face requirements under the regulation; upper bound estimate of total compliance costs that a firm may incur									
50 MGD All Waterbodies	100	54	54	46	46	0	0	0	0
200 MGD All Waterbodies	100	86	86	14	14	0	0	0	0
100 MGD Certain Waterbodies	100	88	88	12	12	0	0	0	0
Other Industries									
50 MGD All Waterbodies	14	10	71	4	29	0	0	0	0
200 MGD All Waterbodies	14	13	93	1	7	0	0	0	0
100 MGD Certain Waterbodies	14	13	93	1	7	0	0	0	0

As presented in Exhibit VIII–6, EPA estimated that the number of firms owning regulated facilities in the Primary Manufacturing Industries range from 100 (Case 2 estimate) to 313 (Case 1 estimate), depending on the assumed ownership cases outlined above. An additional 14 firms are known to own facilities in Other Industries. No firms are estimated to incur total compliance costs equal to or exceeding 1 percent of revenue under any of the regulatory options.

b. Electric Generators

All Electric Generators with a design intake flow of 50 MGD or greater were already covered by the final Phase II regulation. As a result, no Electric Generators are subject to the national categorical requirements of the three co-proposed options.

B. New Offshore Oil and Gas Extraction Facilities

1. Overview of Affected Industry Sectors

The proposed rule establishes requirements for new facilities that would apply to new offshore oil and gas extraction facilities that employ a cooling water intake structure (CWIS) and are designed to withdraw greater than 2 million gallons per day (MGD) from waters of the United States.[44] Offshore oil and gas extraction facilities (''Oil and Gas Facilities'') are facilities primarily engaged in oil and gas production and drilling activities. This analysis includes oil and gas production platforms/structures and mobile offshore drilling units (MODUs). EPA estimates that 21 new oil and gas extraction platforms and 103 new MODUs would be subject to the national requirements of the proposed option, assuming a 20-year period of construction from 2007 (the assumed effective date of the rule) to 2026. Each newly-constructed facility is assumed to operate for 30 years, extending the entire analysis period over 49 years (2007 to 2055). Different methods of discounting over time are used for the social cost and impact analyses. Social costs are discounted to 2007, the assumed effective date of the rule, and then annualized over 30 years using 3% and 7% discount rates. For the impact analysis, compliance costs are discounted for each individual facility to the year of compliance (the year the vessel is launched or the platform/structure comes on line, which ranges from 2007 to 2026) and then summed to produce an aggregate present value of compliance costs. This aggregate present value is then annualized over 30 years using 3% and 7% discount rates.

2. Social Cost for New Offshore Oil and Gas Extraction Facilities

The total annualized social cost of the proposed option for new Oil and Gas facilities is estimated at $3.7 million using a 3 percent discount rate, and $3.0 million using a 7 percent discount rate. The largest component of social cost is the pre-tax cost of regulatory compliance incurred by complying facilities; these costs include one-time technology costs of complying with the rule, annual operating and maintenance costs, and permitting costs (initial permit costs, annual monitoring costs, and permit reissuance costs). Social cost also includes implementation costs incurred by the Federal government. EPA expects that for the most part, the proposed regulation would be implemented under general permits, two in the Gulf of Mexico, and one in Cook Inlet Alaska.[45] States are thus not likely to be involved in administering the permits for new regulated offshore oil and gas facilities because the facilities in the Gulf of Mexico operate in non-State waters (beyond the 3-mile limit) and Alaska does not have NPDES authority. EPA requests comment on its projections about the operating locations of new facilities.

EPA estimates that direct compliance costs would be $3.2 million and $2.7 million, using a 3 percent and 7 percent discount rate, respectively. The estimated Federal government cost for administering the rule for new facilities is comparatively minor in relation to the estimated direct cost of regulatory compliance. Federal administrative costs are estimated to be $0.4 million and $0.3 million per year under the 3 percent and 7 percent discount rates, respectively.

3. Economic Impacts for New Offshore Oil and Gas Extraction Facilities

The following two subsections present economic impacts for MODUs and production platforms/structures, respectively. Certain aspects of the methodology differ between the two segments. Oil and gas production operations involve production of a finite resource, which limits the potential life of a production platform. Thus, the analysis for production platforms/structures must account for the production and resulting exhaustion of the finite oil and gas resource. Key considerations in the platforms analysis are: (1) When does production

[44] *See* section II.B for a definition of a new offshore oil and gas extraction facility for the purposes of this proposal.

[45] Because individual permits are not issued, costs for pre-permitting and re-permitting studies are assumed to be shared among groups of new facilities expected to be covered by the general permits (*see* DCN 7–4036 for detailed information on how permitting costs are assumed to be shared under the general permits).

terminate? and (2) would the year of termination change due to regulation? The economic life of a MODU is not limited by such considerations and the analysis for MODUs is accordingly simpler. The EA and the rulemaking record contain additional data and details on the methodology and assumptions used in these analyses.

a. MODUs

EPA projects that 80 new jackups, 20 new semi-submersibles, and three new drill ships will be constructed over the 20 years for which new facility additions are analyzed. The economic impact analysis for these new MODUs is conducted at two levels: the vessel level and the firm level. EPA conducted two vessel-level analyses and one firm-level analysis:

- The first vessel-level analysis is a closure analysis, which assesses changes in vessel cash flow and net income. Because the financial condition of new vessels is unknown, EPA used financial information from representative existing vessels, collected in EPA's 316(b) survey of MODUs (DCN 7–0008), to represent the financial characteristics of new facilities. The financial information from these representative vessels is used for a general assessment of how well these vessels would perform financially if costs of the proposed option applied. This analysis is used as an alternative assessment of the potential for a barrier to entry.
- The second vessel-level analysis is a standard barrier-to-entry analysis for new facilities. This analysis computes the present value of estimated initial permitting costs, which are assumed to be incurred over five years prior to the incorporation of section 316(b) permit requirements in the applicable general permits (see DCN 7–4036) and are discounted to the year of compliance (the year the vessel is assumed to be launched). The one-time capital costs of compliance (assumed to be incurred in the year of compliance) are then added to this figure. These summed compliance costs are then compared to the baseline construction costs for each type of MODU. Neither recurring costs of compliance (*e.g.*, repermitting costs or recurring capital costs of CWIS controls) nor recurring baseline costs (*e.g.*, O&M, refitting costs) are considered in this analysis. The analysis compares baseline start-up costs and incremental start-up costs associated with the proposed rule.
- The firm-level analysis is a cost-to-revenue test which compares the annualized compliance costs for representative new vessels to the revenues of firms likely to construct MODUs, assuming each of these firms builds a share of the 103 new MODUs expected to be constructed over the 20-year construction time frame. This analysis was conducted on a pre-tax and after-tax basis.

i. Vessel-Level Closure Analysis

To estimate potential closures (or more precisely, decisions not to proceed with constructing and placing a vessel into service) as a result of today's proposal for new MODUs, EPA used two models: (1) A net income model, which computes the estimated present value of baseline after-tax net income (*i.e.*, without compliance costs) for representative MODUs (based on survey data from existing MODUs) over a 30-year operating period for each new facility,[46] and (2) an after-tax cost calculation model, which estimates the present value of after-tax compliance costs using engineering and permitting cost inputs. Comparing the results of these two models shows the potential effect of costs on vessel net income.

EPA estimated after-tax net income for eight MODUs, using data provided by surveyed operators of existing MODUs (EPA received economic surveys for three semi-submersibles, three jackups, and two drill ships). EPA was only able to undertake financial analysis for those MODUs with a positive net income for the three years of financial information provided in the survey (2000 to 2002). EPA assumed that any MODU whose net income is negative over the three years is unlikely to be a viable operation in the baseline and cannot be analyzed with respect to compliance costs.

EPA used the net income over the three years of survey data to create a moving cycle of net income over the period of analysis. Among the years of data collected (2000 to 2002), 2002 was generally a poor year of financial condition for the industry as a whole. EPA was thus able to represent industry financials in both good and bad years. The three-year cycle simulates the effect of volatility in oil and gas prices and other business conditions (*e.g.*, rig utilization rates) over each facility's 30-year operating period. Future operating periods are likely to include major swings in the prices of oil and gas, the driving force behind the level of operations, rig pricing, and, thus, financial performance of the newly constructed vessels. EPA assumed that net income will be flat, on a three-year average basis, over the 30 years of analysis and thus did not apply any factors to increase or decrease net income over the years of analysis. The net income figures from the survey, therefore, repeat every three years for 30 years. EPA then computed the present value of that stream of net income and compared it to the present value of after-tax compliance costs for the proposed option.

EPA used the estimated compliance cost elements—capital, O&M, and permitting costs—for each new MODU to calculate the present value of the after-tax cost of compliance with today's proposed requirements. Each compliance-related cost was accounted for in the year it is assumed to be incurred. Tax effects of compliance outlays were based on the owner company's marginal tax rate as determined from the firm's average taxable earnings over the three years of survey data (converted to a mid-year 2003 basis). EPA calculated depreciation for the compliance capital outlay using the modified accelerated cost recovery system (MACRS) and included it in the pre-tax compliance cost stream. The compliance cost stream was then reduced by the amount of avoided tax liability, based on the estimated marginal tax rate, to yield the after-tax compliance cost stream (for more information on these calculations, see DCN 7–4016). The final result of these calculations is the present value of after-tax compliance costs.

The present value of after-tax compliance costs was then subtracted from the present value of baseline net income for the vessel. If the present value of net income remained positive

[46] Consistent with generally accepted methods of business value analysis, EPA would have preferred to use the present value of after-tax cash flow instead of net income as the basis for this analysis. However, because it could not reliably estimate all of the elements of cash flow, the Agency instead used the present value of net income for its closure test. In particular, EPA was unable to estimate the ongoing capital outlays (apart from those resulting from regulatory compliance) that MODUs would need to make as part of their ordinary business operations. In performing the analysis in this way, the Agency essentially used the facility's reported depreciation and amortization—which, being non-cash items, are normally excluded from cash flow accounting—as an approximation of ongoing capital outlays. How use of reported depreciation and amortization, instead of a reliable estimate of capital outlays, affects the findings from this analysis cannot be precisely known. For some businesses—in particular those with relatively strong financial performance—depreciation and amortization may be less than ongoing capital outlays; for these businesses, the analysis will tend to overstate business value and understate the potential effect of compliance outlays on financial performance and business value. On the other hand, for some businesses—in particular those with relatively weak financial performance—depreciation and amortization may exceed ongoing capital outlays; for these businesses, the analysis will tend to understate business value and overstate the potential effect of compliance outlays on financial performance and business value.

after accounting for compliance costs, EPA assumed that the MODU would operate post-compliance. If the present value of net income became negative, EPA assumed that the new MODU would not be a financially viable project and was counted as a potential ''regulatory closure.''

The analysis is based on the assumption that costs cannot be passed through to customers. Because existing MODUs will not have to meet the requirements of the proposal, and new MODUs must compete with these existing MODUs, assuming zero cost pass-through provides a realistic estimate of potential economic impacts on new MODUs.

This analysis found that no new MODUs (based on an assumption that finances for new MODUs will look like those for existing MODUs) would be a regulatory closure as a result of the incremental compliance costs associated with the proposed option (detailed results are provided in the CBI portion of today's record; DCN 7–4020).

ii.Vessel-Level Barrier-to-Entry Analysis

The barrier-to-entry analysis compares the present value of compliance costs (including the present value of initial permitting costs discounted to the compliance year and first-time capital/installation costs, excluding recurring costs), to the costs of constructing a new MODU. If compliance costs comprised a small fraction of construction costs, EPA assumed that compliance costs would have no effect on the decision to build a new MODU.

EPA developed incremental compliance costs for new MODUs using estimated initial permitting costs and technology cost estimates. The initial permitting costs are based on each new MODU's share of regional permitting costs (EPA expects that facilities in a particular geographic region would collect data from representative facilities in that region) and individual administrative start-up and permit application costs. The technology costs are based on the weighted average cost of installing controls at existing MODUs, by type of MODU, for all existing MODUs with technical data. The estimated present value of the initial permitting cost stream, plus the first-time capital/installation costs of compliance costs, sum to $127,000 for semi-submersibles, $258,000 for jackups, and $247,000 for drill ships. According to IADC (May/June, 2003), the cost of new MODUs planned to be built in the next few years averages $250 million for semi-submersibles and $125 million for jackups. A drill ship completed in 1998 cost approximately $275 million (R&B Falcon's Pathfinder). The present value of initial permitting costs plus one-time capital/installation compliance costs is therefore estimated to range from 0.05 percent to 0.21 percent of construction costs for the three types of MODU. Because total up-front costs represent a very small fraction of total costs of construction (and even of contingency costs, which typically range from 10 percent to 20 percent of capital costs), EPA believes that these costs would not have a material effect on decisions to build new MODUs.

iii. Firm-Level Cost-to-Revenue Analysis

EPA's research showed that firms likeliest to build MODUs with a design intake flow of greater than 2 MGD are those that currently own such MODUs. EPA identified seven firms owning jackups, semi-submersibles, or drill ships that would be subject to the proposed requirements for new facilities if newly constructed. They also are among the largest firms in the industry and are thus likely to be involved in new construction. EPA estimates that these seven firms would own the 103 new MODUs subject to the proposed national requirements for new facilities. To determine the potential impact of the proposed option on the seven firms determined likely to build new MODUs subject to regulation, EPA used a cost-to-revenue test, which compares the annualized pre-tax and after-tax costs of compliance (calculated for representative new MODUs), with 2002 revenues reported by these firms. Because nearly all of the firms (other than foreign-owned) are publicly owned, EPA relied on revenue data compiled from corporate 10K reports (see Chapter C2 of the EA). EPA then assigned a number of MODUs potentially subject to regulation to each of the firms and used the average per-MODU compliance costs multiplied by the number of these MODUs to calculate the total compliance costs that might be faced by these firms.

Estimated total annual pre-tax compliance costs are approximately $15,000 for a semi-submersible, $33,000 for a jackup, and $37,000 for a drill ship. Estimated after-tax costs are approximately $10,000, $21,000, and $24,000, respectively, based on a 35 percent marginal corporate tax rate assumption. These annualized costs are very small compared to the revenues a MODU might receive for drilling even one exploratory well in deepwater, which could approach $25 to $30 million (DCN 7–4017). They are also small compared to the typical day rates (daily charges) paid to MODUs while drilling wells. These rates can range from $150,000 to $250,000 per day (DCN 7–4042). Five firms are assumed to build 12 jackups or semi-submersibles over the time frame of the analysis (approximately one MODU every other year). The two additional firms, GlobalSantaFe and Transocean, are the dominant firms in the industry. These two firms are each assumed to build 20 jackup or semi-submersibles, plus one drill ship and two drill ships, respectively, over the time frame of the analysis for a total of 21 or 22 MODUs in total. EPA used the higher cost of a jackup rig to represent the cost of compliance for both jackups and semi-submersibles. For simplicity, and to be conservative, EPA assumed that the annualized costs of compliance for all MODUs constructed over the period of analysis by each firm are incurred in one year for comparison to one year's revenues.

Using these assumptions, EPA estimates that the annualized pre-tax costs per firm range from $0.4 to $0.7 million, and the after-tax costs range from $0.3 to $0.5 million. The pre-tax cost-to-revenue ratio ranges from 0.03 percent to 0.06 percent, while the after-tax ratios range from 0.02 percent to 0.04 percent. Given that the highest estimated ratio is 0.06 percent, EPA concludes that firm-level impacts would not pose a barrier to entry.

b. Oil and Gas Production Platforms

EPA projects that 20 deepwater platforms and one Alaska platform will be constructed over the 20 years over which new facility additions are analyzed. The economic impact analysis for these new platforms is conducted at two levels: the platform level and the firm level. EPA conducted two platform-level analyses and one firm-level analysis:

- The first platform-level analysis assesses the potential effects of compliance costs on platform operation. Two effects of the proposed option are considered: (1) A reduction in the expected economic value of the platform, driven by all costs of compliance, which could prevent oil and gas resources from being brought into production, and (2) earlier production shut-in, driven by the increase in O&M costs. The baseline operating and financial profile for this analysis is based on data from existing platforms whose cooling water intake rates would cause them to be subject to the proposed rule if they were being newly constructed after rule promulgation. These existing platforms serve as a baseline model of the

operating and financial conditions of new platforms that would be regulated under the proposal. Estimated compliance costs are added to the baseline cost profile in the analysis of compliance costs on platform operations.

- The second platform-level analysis is a barrier-to-entry analysis for new facilities. This analysis compares the present value of estimated initial permitting costs plus the one-time capital costs of compliance (excluding any recurring costs) to the construction costs for each type of platform.
- The firm-level analysis is a cost-to-revenue test, which compares the annualized compliance costs for representative new platforms to the revenues of firms likely to construct new platforms/structures. This analysis assumes that each firm likely to build a deepwater platform/structure subject to regulation would bring four platforms/structures on line over the time frame of the analysis; and that only one firm will build an Alaska platform during the analysis period. For simplicity and to be conservative, firms assumed to bring four deepwater structures on line are assigned the annualized costs of compliance for four platforms in one year for comparison against one year's revenues. This analysis was conducted on a pre-tax and after-tax basis.

i. Platform-Level Production/Shut-In Analysis

Compliance costs resulting from the proposed option may affect a platform's financial performance and related operating decisions in two ways. First, increased costs from regulatory compliance will reduce the expected economic value of an oil and gas production project, and may prevent an otherwise financially viable project from being undertaken. Second, even if a project overall remains financially viable, increased operating costs may lead to an earlier production shut-in than would occur in the baseline. Details of the analysis of these effects are provided below.

For the analysis of these effects, EPA constructed a general platform analysis model, which simulates the operations and economics of oil and gas development and production. The platform model analyzes production over a period extending as long as 30 years. Pre-tax costs (including costs incurred in pre-production years, O&M, monitoring costs, and repermitting costs) are input into the model in the year in which they occur, until the model shows the platform is uneconomical to operate. To determine the shut-in year, projected net revenue is compared to operating costs in each production year. Net revenue is based on an assumed price of oil, current and projected production of oil and gas, well production decline rates, and severance and royalty rates. Operating costs are based on a calculated cost per barrel of oil equivalent (BOE) produced. The model simulates operations for the lesser of 30 years or to the year when operating costs exceed production revenue, at which point the operator is assumed to terminate production. The model calculates the lifetime of the project, total production, and the net present value of the operation (net income of the operation over the life of the project in terms of today's dollars). A comparison of the baseline model outputs to the post-compliance model outputs yields any losses of production and project lifetimes and the net present value of the operation. If the net present value of the operation is positive in the baseline but negative post-compliance, the project is considered nonviable post-compliance. It is assumed the platform would not be built.

The model uses as baseline data, financial information from representative existing platforms, collected in EPA's 316(b) survey of production platforms (DCN 7–0008) to represent the financial characteristics of future platforms that would be subject to this proposed regulation. EPA received an economic survey from only one deepwater platform with cooling water intake structure flows meeting the proposed regulatory criteria. EPA used data from this survey and from other sources of publicly available information, such as the Minerals Management Service, to develop a model new deepwater oil and gas production platform. EPA also received a survey from a platform in Alaska but did not include it in the analysis because the surveyed platform is a very old structure and at the end of its productive life. It is likely that it would not be representative of new platforms being built after the Phase III rule is finalized. The Alaska platform is therefore analyzed only in the barrier to entry analysis.

Analysis of Project Viability

As noted above, any increase in costs, whether operating, capital, or permitting, will reduce the expected economic value of an oil and gas project, as represented by the present value of project net income, and may cause an otherwise economic oil and gas production project to never be undertaken. In this case, the entire economic value of the project and its otherwise recoverable oil and gas production are assumed to be lost (note: this loss need not be permanent but may only be delayed until higher product prices, or reduced development and production costs allow the project to become financially viable). For this potential impact, EPA analyzed whether the reduction in value from all regulatory compliance outlays would be sufficient to cause the expected discounted net income of an otherwise economically viable oil and gas production project to be negative—at the outset. In this case, the operator is assumed not to proceed with development and production. If the platform has a positive net present value under baseline conditions but a negative net present value in the post-compliance scenario, EPA notes an impact on the platform and estimates the lost production resulting from the costs of regulatory compliance.

Analysis of Production Shut-In Effects

Although a project overall remains financially viable, the increased operating costs from regulatory compliance may lead to an earlier production shut-in than would occur in the baseline. Shut-in refers to lost production from non-production of producible reserves for reasons such as tests, repairs, or to await construction of gathering lines. Apart from the financial impact, an earlier shut-in will also lead to reduced production of otherwise economically recoverable oil and gas. For this analysis, projected net revenue is compared to operating costs at each year for the model project.[47] Net revenue (after subtracting royalties and severance, which are payments to the lease owner and a State, if relevant) is based on an assumed price of oil, current and projected production of oil and gas, well production decline rates, and severance and royalty rates. Operating costs are based on a calculated cost per barrel of oil equivalent (BOE) produced. The model simulates operations for the lesser of 30 years or to the year when operating costs exceed production revenue, at which point the operator is assumed to terminate production. A comparison of total production and total project lifetime in the baseline vs. post-compliance shows any differences in these variables following the imposition of compliance costs.

[47] Following engineering review of surveyed deepwater platforms/structures, only one was determined to have a total design CWIS intake flow rate meeting the proposed 316(b) thresholds for regulation of oil and gas facilities, had the structure been newly constructed, so only one model of deepwater structures was developed.

This analysis found no impacts on deepwater oil and gas development or production as a result of the incremental compliance costs associated with the proposed option for the one platform that was analyzed. Impacts on net present value were very small. (Detailed results are included in the CBI portion of today's record; DCN 7–4038.)

ii. Platform-Level Barrier-to-Entry Analysis

The barrier-to-entry analysis compares the present value of the initial permitting cost stream (discounted to the year of compliance) plus one-time capital/installation costs to the costs of constructing a new platform. If compliance costs comprise a small fraction of construction costs, EPA assumes that compliance costs would not have an effect on the decision to build a new platform.

The estimated total present values of incremental compliance costs are $291,000 for deepwater projects and $685,000 for Alaska projects. Costs for constructing new deepwater platforms are estimated to range from $114 million to $2.3 billion (see EA for the Synthetic Drilling Fluid Effluent Limitations Guidelines in the rulemaking record, DCN 7–4017). For Alaska, EPA used a value of $120 million (DCN 7–4028). The ratio of incremental compliance costs to current total construction costs therefore ranges from 0.01 percent to 0.3 percent for deepwater projects and 0.6 percent for an Alaska project. Because this represents a small fraction of total construction costs (and even of contingency costs), EPA believes that these costs would not have a material effect on decisions to build new platforms.

iii. Firm-Level Cost-to-Revenue Analysis

To determine the potential impact of the proposed option on firms, EPA used a cost-to-revenue test, which compares the annualized pre-tax and after-tax costs of compliance (calculated for a representative new platform times the maximum number of platforms assumed built by each firm in any one year), with 2002 revenues reported by all firms determined likely to be affected by this regulation. The firms that are considered affected are (1) those identified as currently having existing deepwater platforms or structures that would be subject to regulation if they were newly constructed and (2) the likeliest type of firm to build a new Alaska platform during the time frame of the analysis. EPA assumed each of the five firms operating in the deepwater Gulf would bring on-line four platforms during the period of analysis (for a total of 20 platforms). For simplicity and to be conservative, EPA assumes the four platforms come on line in one year for comparison with one year's revenues at each firm. One small firm is assumed to build the one Alaska platform over the period of analysis, and the annualized compliance cost is also compared to one year's revenues at that firm.

Using these assumptions, EPA estimates that the annualized pre-tax costs per firm are about $0.3 million, and the after-tax costs are about $0.2 million. The pre-tax cost-to-revenue ratio ranges from <0.001 percent to 0.01 percent, while the after-tax ratios range from <0.001 percent to 0.007 percent. Given that the highest estimated ratio is 0.01 percent, EPA concludes that firm-level impacts would not pose a barrier to entry.

c. Total Facility Compliance Costs and Impacts for All New Offshore Oil and Gas Extraction Facilities

Exhibit VIII–7 summarizes the total facility compliance costs and impacts associated with the proposed option for Phase III new offshore oil and gas extraction facilities. Annualized after-tax costs total $1.8 million per year for MODUs and $1.2 million per year for platforms, or a total of $3.1 million per year for all affected new oil and gas operations estimated to be constructed over the period of the analysis (using a 7 percent discount rate).[48]

EXHIBIT VIII–7.—SUMMARY OF PRIVATE COSTS AND IMPACTS FOR NEW OIL AND GAS FACILITIES

Type of O&G facility	Number of new facilities	Annualized private after-tax compliance costs (in millions, 2003 $)	Facility impacts	Firm impacts
MODUs	103	$1.8	0	0
Platforms	21	1.2	0	0
Total	124	3.1	0	0

Note: Component values may not sum to the reported total due to independent rounding.

C. Summary of Total Social Costs and Impacts

As discussed earlier, EPA is proposing national categorical requirements for existing Phase III facilities, as defined by one of the three co-proposed flow-threshold-based options, and is proposing requirements similar to certain provisions of the rule for new offshore oil and gas extraction facilities. EPA estimated a total annualized social cost for the ''50 MGD for All Waterbodies'' option for existing facilities and the proposed option for new oil and gas extraction facilities of $51.0 million at a 3 percent discount rate, and $53.1 million, at a 7 percent discount rate. EPA estimates that 260 facilities would be subject to national requirements and that none of these facilities would experience adverse impacts. Exhibit VIII–8 summarizes these findings.

[48] Costs are incurred assuming 20 years of new facility construction, with each facility incurring costs over a 30-year operating period, discounted to the year the facility is launched or comes on-line. The present value of private after-tax costs is less than the previously described present value of social costs, which are based on pre-tax costs, because of differences in the discounting for private costs and social costs. Private costs are discounted, for each analysis, only to the first year of compliance. In contrast, for the social cost calculation, all costs are discounted to the beginning of 2007, regardless of when new facilities come into operations. Because new facilities are scheduled to begin operation for a 20 year period following rule promulgation, the total effect of discounting is much greater for the present value of social cost calculation than for the private cost calculation. As a result, the present value of social costs, even though based on pre-tax costs, is less than the present value of private, after-tax cost.

EXHIBIT VIII–8.—SUMMARY OF ECONOMIC ANALYSIS: ''50 MGD FOR ALL WATERBODIES'' OPTION FOR EXISTING FACILITIES PLUS NEW OFFSHORE OIL AND GAS FACILITIES > 2 MGD

	Annualized social cost (in millions, 2003 $)		Number of facilities subject to national equirements	Number of facilities with impacts*
	3% Discount rate	7% Discount rate		
Direct Compliance Cost:				
Manufacturing Industries	$42.7	$45.1	127	0
Other Industries	4.1	4.4	9	0
Electric Generators	N/A	N/A	N/A	N/A
New O&G Facilities	3.2	2.7	124	0
Total	50.0	52.2	260	0
State and Federal Administrative Cost	1.0	0.9	.....	.....
Total Social Cost	51.0	53.1	.....	.....

* The impact measures for existing Manufacturers are facility closure and moderate financial impact (see also section VIII.A.3.a). The two impact measures for new Oil and Gas facilities are facility closures and barrier to entry (see also section VIII.B.3). Numbers may not add up to totals due to independent rounding.

EPA estimated a total annualized social cost for the ''200 MGD for All Waterbodies'' option for existing facilities and the proposed option for new oil and gas extraction facilities of $26.4 million at a 3 percent discount rate, and $27.2 million, at a 7 percent discount rate. EPA estimates that 149 facilities would be subject to national requirements and that none of these facilities would experience adverse impacts. Exhibit VIII–9 summarizes these findings.

EXHIBIT VIII–9.—SUMMARY OF ECONOMIC ANALYSIS: ''200 MGD FOR ALL WATERBODIES'' OPTION FOR EXISTING FACILITIES PLUS NEW OFFSHORE OIL AND GAS EXTRACTION FACILITIES

	Annualized social cost (in millions, 2003 $)		Number of facilities subject to national requirements	Number of acilities with impacts*
	3% Discount rate	7% Discount rate		
Direct Compliance Cost:				
Manufacturing Industries	$21.7	$23.1	23	0
Other Industries	1.0	0.9	2	0
Electric Generators	N/A	N/A	N/A	N/A
New O&G Facilities	3.2	2.7	124	0
Total	25.9	26.7	149	0
State and Federal Administrative Cost	0.5	0.4	.....	.....
Total Social Cost	26.4	27.2	.....	.....

*The impact measures for existing Manufacturers are facility closure and moderate financial impact (see also section VIII.A.3.a). The two impact measures for new Oil and Gas facilities are facility closures and barrier to entry (see also section VIII.B.3). Numbers may not add up to totals due to independent rounding.

EPA estimated a total annualized social cost for the ''100 MGD for Certain Waterbodies'' option for existing facilities and the proposed option for new oil and gas extraction facilities of $21.3 million at both a 3 percent and 7 percent discount rate. EPA estimates that 143 facilities would be subject to national requirements and that none of these facilities would experience adverse impacts. Exhibit VIII–10 summarizes these findings.

EXHIBIT VIII–10.—SUMMARY OF ECONOMIC ANALYSIS: ''100 MGD FOR CERTAIN WATERBODIES'' OPTION FOR EXISTING FACILITIES PLUS NEW OFFSHORE OIL AND GAS EXTRACTION FACILITIES

	Annualized social cost (in millions, 2003 $)		Number of facilities subject to national requirements	Number of facilities with impacts*
	3% Discount rate	7% Discount rate		
Direct Compliance Cost:				
Manufacturing Industries	$16.7	$17.4	17	0
Other Industries	0.7	0.7	2	0
Electric Generators	N/A	N/A	N/A	N/A
New O&G Facilities	3.2	2.7	124	0

EXHIBIT VIII–10.—SUMMARY OF ECONOMIC ANALYSIS: ''100 MGD FOR CERTAIN WATERBODIES'' OPTION FOR EXISTING FACILITIES PLUS NEW OFFSHORE OIL AND GAS EXTRACTION FACILITIES—Continued

	Annualized social cost (in millions, 2003 $)		Number of facilities subject to national requirements	Number of facilities with impacts*
	3% Discount rate	7% Discount rate		
Total	20.7	20.8	143	0
State and Federal Administrative Cost	0.6	0.5	.....	.....
Total Social Cost	21.3	21.3	.....	.....

*The impact measures for existing Manufacturers are facility closure and moderate financial impact (see also section VIII.A.3.a). The two impact measures for new Oil and Gas facilities are facility closures and barrier to entry (see also section VIII.B.3). Numbers may not add up to totals due to independent rounding.

IX. Benefits Analysis

A. Introduction

This section presents EPA's estimates of the national economic benefits of the three co-proposed regulatory options for the section 316(b) regulation for Phase III existing facilities: The ''50 MGD for All Waterbodies'' option, the ''200 MGD for All Waterbodies'' option, and the ''100 MGD for Certain Waterbodies'' option. The benefits occur due to the reduction in impingement mortality and entrainment at cooling water intake structures affected by this rulemaking (see section II for a description of the facilities to which this rulemaking potentially applies). By reducing impingement mortality and entrainment, the co-proposed options would increase the number of fish, shellfish, and other aquatic life in local aquatic ecosystems. This, in turn, will directly and indirectly generate use benefits such as those associated with recreational and commercial fishing. Other types of benefits that are independent of any current or anticipated uses of the resource could also be realized; these are known as non-use values. Section IX.D provides an overview of types and sources of benefits anticipated, how these benefits were estimated, and what level of benefits have been estimated for each of the three co-proposed options. For a comparison of social benefits and total social costs, refer to Section X.

To estimate the economic benefits of reducing impingement mortality and entrainment at cooling water intake structures, all the beneficial outcomes need to be identified and, where possible, quantified and assigned appropriate monetary values. Estimating economic benefits can be challenging because of the many steps of analysis that are necessary to link a reduction in impingement mortality and entrainment to changes in impacted fisheries and other aspects of relevant aquatic ecosystems, and then to link these ecosystem changes to the resulting changes in quantities and values for the associated environmental goods and services that ultimately are linked to human welfare. The methodologies used in the estimation of benefits of the proposed regulatory options are largely built upon those used for estimating benefits of the final rule for Phase II facilities (*see* 69 FR 41576). *The Regional Benefits Assessment for the Proposed Section 316(b) Rule for Phase III Facilities* (see DCN 7–0003), hereafter known as the Regional Analysis Document, provides EPA's analyses for the benefit assessment for the proposed options.

The benefit estimates for this rule are derived from a series of regional studies for a range of waterbody types throughout the U.S. Section IX.B provides detail on the regional study design. Sections IX.C and IX.D describe the methods EPA used to estimate impingement mortality and entrainment impacts at potentially regulated existing facilities and to derive an economic value of such losses. National benefits were estimated using a set of statistical weights for each potentially regulated facility. The weights were developed as part of EPA's design of the survey of the industries.

The benefit estimates presented in the following sections reflect changes in impingement mortality and entrainment reductions at existing facilities only. EPA was unable to assess benefits of reducing impingement and entrainment at new offshore oil and gas extraction facilities due to significant data gaps at the time of proposal. Therefore, the benefits estimates presented in this section should be compared only to the cost estimates for existing Phase III facilities. EPA solicits submission of data on impingement mortality and entrainment impacts at offshore oil and gas extraction facilities.

B. Study Design and Methods

EPA's evaluation of impingement mortality and entrainment data had four main objectives: (1) To develop a national estimate of the magnitude of impingement and entrainment at potentially regulated facilities; (2) to standardize impingement and entrainment rates using common biological metrics so that rates could be compared across species, years, facilities, and geographical regions; (3) to estimate changes in these metrics as a result of projected reductions in impingement and entrainment under the proposed rule options; and (4) to obtain data that can be used to estimate the national economic benefits of reduced impingement and entrainment.

Harvested species were the main focus of EPA's analysis, primarily because of the availability of economic methods for valuing these species. EPA's approach to estimating changes in harvest assumed that impingement and entrainment losses result in a reduction in the number of harvestable adults in the years following the time that individual fish are killed by impingement and entrainment and that future reductions in impingement and entrainment will lead to future increases in fish harvest. This approach only estimates the incremental yield that is foregone because of the number of deaths due to impingement and entrainment and is not intended to provide an estimate of absolute population levels. EPA intends to investigate the feasibility of applying a population modeling approach to estimate expected changes in harvest levels and fish population sizes. Such an approach would use available data and life-stage specific estimates of natural mortality, impingement and entrainment mortality, and fishing mortality, plus an explicit function describing density-dependent reproductive success to attempt to estimate long-term changes in average

harvest levels and stock sizes. A population model could serve as a supplement or as an alternative to the current modeling approach based on age one equivalent losses. EPA invites comment on ways that it might develop a population model to support an estimate of the national benefits of this rulemaking.

1. Extrapolation of Impingement and Entrainment Rates

To obtain a national estimate of losses at all potentially regulated facilities, it was necessary to extrapolate impingement and entrainment rates from facilities with data (model facilities) to facilities without data. Extrapolation of impingement and entrainment rates was necessary because not all potentially regulated facilities within a given region have conducted impingement and entrainment studies. Model facilities included both Phase II facilities and potentially regulated Phase III facilities,[49] based on the assumption that impingement and entrainment rates at Phase II and Phase III facilities are similar after normalization by intake flow. Phase II facilities were included to make use of the largest possible data set and to accommodate the lack of impingement and entrainment data from potentially regulated Phase III facilities in some regions. Impingement and entrainment data from 72 Phase II facilities and 16 potentially regulated Phase III facilities were evaluated.

Impingement and entrainment data were extrapolated on the basis of operational intake flow in millions of gallons per day (MGD), where MGD is the average operational flow over the period 1996–1998 as reported by facilities in response to EPA's survey of the industry. Operational flow at each facility was rescaled using factors reflecting the relative effectiveness of currently in-place technologies for reducing impingement and entrainment. The extrapolation procedure is described in Chapter A1 of Part A of the *Regional Analysis Document.* While there may be variations from these estimates in the actual losses (and benefits) per MGD across individual facilities, EPA believes that this method of extrapolation is a reasonable basis for developing an estimate of national-level benefits.

2. Study Regions and Facilities

EPA's analysis examined cooling water intake structure impacts and regulatory benefits at the regional scale, and then combined regional results to develop national estimates. The Agency evaluated the benefits of the proposed regulatory options in six study regions based on the locations of potentially regulated Phase III facilities and similarities in the affected ecosystems, aquatic species present, and characteristics of commercial and recreational fishing activities within each region. The four coastal regions (California, North Atlantic, Mid-Atlantic, and Gulf of Mexico) correspond to those of the National Oceanographic and Atmospheric Association (NOAA) Fisheries agency (formerly the National Marine Fisheries Service). The Great Lakes region includes all potentially regulated Phase III facilities that withdraw water from Lakes Ontario, Erie, Michigan, Huron, and Superior, or are located on a waterway with open fish passage to a Great Lake and within 30 miles of the lake. The Inland region includes the remaining facilities that withdraw water from freshwater lakes, rivers, and reservoirs. Exhibit IX–1 indicates the number of potentially regulated Phase III facilities in each study region. The exhibit also shows the number of facilities subject to national technology requirements under each of the co-proposed regulatory options.

EXHIBIT IX–1.—PHASE III FACILITIES IN EACH REGION

Region	Number of potentially regulated existing phase III facilities [a] (weighted)	Number of facilities subject to national technology requirements under proposed regulatory options [b] (weighted)		
		50 MGD all waterbodies	200 MGD all waterbodies	100 MGD certain waterbodies
California	9	1	0	0
North Atlantic	5	4	1	3
Mid-Atlantic	13	3	2	2
South Atlantic	4	0	0	0
Gulf of Mexico	11	7	2	7
Great Lakes	68	19	5	6
Inland	493	69	12	0
Total, Study Regions	599	103	22	18
National total [c]	603	103	22	18

[a] Potentially regulated existing Phase III facilities include electric generators with CWIS that withdraw more than 2 MGD but less than 50 MGD and manufacturers with CWIS that withdraw more than 2 MGD, that use at least 25% of the water for cooling purposes.
[b] Numbers of facilities reflect only those that are subject to technology requirements; those facilities that only have permitting costs are excluded.
[c] Eighty potentially regulated facilities estimated to close under the baseline scenario are excluded from this analysis.

3. Species Groups

Life history data are very limited for many of the species that are impinged and entrained, and as a result, there are many data gaps for individual species. To overcome this limitation in its national benefit analysis, EPA used available life history data to construct representative life histories for groups of closely related species. Aggregation of species into groups of similar species with a common life history type facilitated parameterization of the fisheries models used by EPA to evaluate facility impingement and entrainment monitoring data. Groups were based on family groups and groups used by NOAA Fisheries for landings

[49] ''Potentially regulated Phase III facilities'' refers to all existing facilities with design intake flows greater than 2 MGD, not regulated in the Phase II rule.

data. For example, bay goby, blackeye goby, yellowfin goby, and other gobies were grouped together as ''gobies.'' An exception was made for species of exceptionally high commercial or recreational value (*e.g.*, striped bass), which were evaluated as single species.

C. Impingement and Entrainment

EPA's analysis is based on facility-provided biological monitoring data. As discussed in Chapter A2 of Part A of the *Regional Analysis Document*, there are several types of uncertainty associated with these data. Major sources of uncertainty are the imperfect precision and accuracy of impingement and entrainment data reported by facilities and of growth and mortality rates obtained from the scientific literature. This results from unavoidable sampling and measurement errors. While these uncertainties may lead to imprecision in impingement and entrainment estimates, EPA found no evidence of statistical bias. Given the goal of its benefit analysis, EPA believes that the data available from facility studies are sufficiently robust for developing estimates of the relative magnitude of impingement and entrainment nationwide.

Using standard fishery modeling techniques,[50] EPA constructed models that combined facility-derived impingement and entrainment counts with relevant life history data to derive estimates of (1) age-one equivalent losses (the number of individuals of different ages impinged and entrained by facility intakes expressed as an equivalent number of age-one fish), and (2) foregone fishery yield (pounds of commercial harvest and numbers of recreational fish and shellfish that are not harvested due to impingement and entrainment). In addition to direct losses of harvested species, estimates of foregone fishery yield include the yield of harvested species that is lost due to losses of forage species, which provide food for harvested species. Details of the methods used to calculate these metrics are provided in Chapter A1 of Part A of the *Regional Analysis Document.* For all analyses, EPA used the impingement and entrainment estimates provided by the facility and assumed 100 percent entrainment mortality based on the analysis of entrainment survival studies presented in Chapter A7 of Part A of the *Regional Analysis Document.* If there is some entrainment survival, this last assumption may lead to some overestimate of baseline entrainment losses.

1. Summary of Current Annual Impingement and Entrainment by Region

Exhibit IX–2 presents EPA's estimates of current annual impingement and entrainment (I&E) in the study regions.

EXHIBIT IX–2.—CURRENT ANNUAL IMPINGEMENT AND ENTRAINMENT, BY REGION

Region	Impingement		Entrainment		Total I & E	
	Age-1 equivalents	Foregone fishery yield (lbs)	Age-1 equivalents	Foregone fishery yield (lbs)	Age-1 equivalents	Foregone fishery yield (lbs)
California	21,000	701	1,290,000	95,100	1,310,000	95,800
North Atlantic	20,100	141	2,320,000	44,800	2,340,000	45,000
Mid-Atlantic	3,890,000	540,000	19,400,000	381,000	23,200,000	920,000
South Atlantic	423,000	49,100	1,090,000	73,700	1,520,000	123,000
Gulf of Mexico	6,140,000	623,000	6,580,000	1,370,000	12,700,000	1,990,000
Great Lakes	31,800,000	413,000	2,570,000	76,400	34,400,000	489,000
Inland	28,600,000	232,000	15,700,000	263,000	44,200,000	495,000
National total[a]	70,900,000	1,860,000	48,900,000	2,300,000	120,000,000	4,160,000

The estimates in Exhibit IX–2 make use of data from available impingement and entrainment studies conducted at both Phase II and Phase III facilities. Using data solely from the limited number of Phase III studies available (4 studies for the Great Lakes region and 11 studies for the Inland region), estimates of loss of age-1 equivalents to impingement and entrainment are 5,160,000 at Great Lakes facilities and 14,700,000 at Inland facilities. Estimates of foregone fishery yield are 16,500 pounds at Great Lakes facilities and 250,000 pounds at Inland facilities.

2. Summary of Annual Reductions in Impingement and Entrainment for Three Options

Exhibit IX–3 presents EPA's estimates of annual impingement and entrainment reductions under the ''50 MGD for All Waterbodies'' option. Exhibit IX–4 presents EPA's estimates of annual impingement and entrainment reductions under the ''200 MGD for All Waterbodies'' option. Exhibit IX–5 presents results for the ''100 MGD for Certain Waterbodies'' option.

a. Reductions in Annual Impingement and Entrainment for the ''50 MGD for All Waterbodies'' Option

See Exhibit IX–3 for reductions in annual impingement and entrainment for the ''50 MGD for All Waterbodies'' option.

[50] Ricker, W.E. 1975. Computation and interpretation of biological statistics of fish populations. Fisheries Research Board of Canada, Bulletin 191; Hilbourn, R. and C.J. Walters. 1992. Quantitative Fisheries Stock Assessment, Choice, Dynamics and Uncertainty. Chapman and Hall, London and New York; Quinn, T.J., II. and R.B. Deriso. 1999. Quantitative Fish Dynamics. Oxford University Press, Oxford and New York; Dixon, D.A. 1999. Catalog of Assessment Methods for Evaluating the Effects of Power Plant Operations on Aquatic Communities. Final Report. Report number TR–112013.

EXHIBIT IX–3.—REDUCTIONS IN ANNUAL IMPINGEMENT AND ENTRAINMENT FOR THE ''50 MGD FOR ALL WATERBODIES'' OPTION, BY REGION

Region	Age-1 equivalents	Foregone fishery yield (lbs)
California	383,000	28,000
North Atlantic	930,000	17,900
Mid-Atlantic	13,400,000	600,000
Gulf of Mexico	8,380,000	1,250,000
Great Lakes	11,600,000	169,000
Inland	14,800,000	157,000
National total	49,500,000	2,220,000

The estimates in Exhibit IX–3 make use of data from available impingement and entrainment studies conducted at both Phase II and Phase III facilities. Using data solely from the limited number of Phase III studies available (4 studies for the Great Lakes region and 11 studies for the Inland region), estimates of reductions in loss of age-1 equivalents to impingement and entrainment are 1,700,000 at Great Lakes facilities and 5,450,000 at Inland facilities. Estimates of reductions of foregone fishery yield are 5,570 pounds at Great Lakes facilities and 93,000 pounds at Inland facilities.

b. Reductions in Annual Impingement and Entrainment for the ''200 MGD for All Waterbodies'' Option

See Exhibit IX–4 for reductions in annual impingement and entrainment for the ''200 MGD for All Waterbodies'' option.

EXHIBIT IX–4.—REDUCTIONS IN ANNUAL IMPINGEMENT AND ENTRAINMENT FOR THE ''200 MGD FOR ALL WATERBODIES'' OPTION, BY REGION

Region	Age-1 equivalents	Foregone fishery yield (lbs)
California	0	0
North Atlantic	198,000	3,800
Mid Atlantic	11,900,000	534,000
Gulf of Mexico	4,580,000	682,000
Great Lakes	7,710,000	116,000
Inland	9,650,000	107,000
National total	34,000,000	1,440,000

The estimates in Exhibit IX–4 make use of data from available impingement and entrainment studies conducted at both Phase II and Phase III facilities. Using data solely from the limited number of Phase III studies available (4 studies for the Great Lakes region and 11 studies for the Inland region), estimates of reductions in loss of age-1 equivalents to impingement and entrainment are 1,100,000 at Great Lakes facilities and 3,270,000 at Inland facilities. Estimates of reductions in foregone fishery yield are 3,690 pounds at Great Lakes facilities and 55,700 pounds at Inland facilities.

c. Reductions in Annual Impingement and Entrainment for the ''100 MGD for Certain Waterbodies'' Option

See Exhibit IX–5 for reductions in annual impingement and entrainment for the ''100 MGD for Certain Waterbodies'' option.

EXHIBIT IX–5.—REDUCTIONS IN ANNUAL IMPINGEMENT AND ENTRAINMENT FOR THE ''100 MGD FOR CERTAIN WATERBODIES'' OPTION, BY REGION

Region	Age-1 equivalents	Foregone fishery yield (lbs)
California	0	0
North Atlantic	754,000	14,500
Mid Atlantic	11,900,000	534,000
Gulf of Mexico	8,380,000	1,250,000
Great Lakes	8,740,000	130,000
National total	29,800,000	1,930,000

The estimates in Exhibit IX–5 make use of data from available impingement and entrainment studies conducted at both Phase II and Phase III facilities. Using data solely from the limited number of Phase III studies available (4 studies for the Great Lakes region), the estimate of reductions in loss of age-1 equivalents to impingement and

entrainment is 1,260,000 and the estimate of reductions in foregone fishery yield is 4,190 pounds at Great Lakes facilities.

d. Reductions in Annual Impingement and Entrainment for Other Policy Options

EPA considered a wide range of policy options in developing the proposed section 316(b) regulation for the Phase III facilities. The Regional Analysis Document provides results for all evaluated options considered in this rulemaking.

D. National Benefits

1. Overview

Economic benefits of the co-proposed options for the section 316(b) regulation for Phase III existing facilities can be broadly defined according to categories of goods and services provided by the species affected by impingement and entrainment by cooling water intake structures.

The first category includes benefits that pertain to the use (direct or indirect) of the affected fishery resources. Use value reflects the value of all current direct and indirect physical uses of a good or service (Mitchell and Carson, 1989; DCN 5–1287). The direct use benefits can be further categorized according to whether or not affected goods and services are traded in the market. The ''direct use'' benefits of the section 316(b) regulation stem both from''market'' commodities (*e.g.*, commercial fisheries) and from ''nonmarket'' goods (*e.g.*, recreational angling). Indirect use benefits also can be linked to either market or nonmarket goods and services—for example, the manner in which reduced impingement and entrainment-related losses of forage species leads through the aquatic ecosystem food web to enhance the biomass of species targeted for commercial (market) and recreational (nonmarket) uses.

The second category includes benefits that are independent of any current or anticipated use of the resource; these are known as ''non-use'' or ''passive use'' values.[51] Non-use values include ''nonmarketed'' goods and services, which reflect human values associated with existence, bequest, and altruistic motives. Existence value is the value that individuals may hold for simply knowing that a particular good exists regardless of their present or expected use. For example, ecological goods and services such as diversity of aquatic and terrestrial species and habitat for threatened and endangered species are often valued for their existence. Bequest value exists when someone gains utility through the knowledge that an amenity will be available for others (family or future generations) in the future (Fisher and Raucher, 1984; DCN 4–0043). Altruistic values arise from interpersonal concerns (valuing the happiness that others get from enjoying the resource).

The economic value of benefits from the proposed options for Phase III facilities is estimated using a range of valuation methods, with the specific approach being dependent on the type of benefit category, data availability, and other suitable factors. Commercial fishery benefits are valued using market data. Recreational angling benefits are valued using a combination of primary and secondary research methods. Methodologies for estimating use values for recreational (non-market values) and commercial (market values) species are well developed, and some of these species have been extensively studied. As a result, these values are relatively easy to estimate. A detailed description of the approaches used for valuing commercial and recreational benefits of the proposed options can be found in Chapters A4 and A5 of the *Regional Analysis Document*.

Estimating benefits from reduced impingement and entrainment of forage species is more challenging because these species are not targeted directly by commercial or recreational anglers and have no direct use values that can be observed in markets or inferred from revealed actions of anglers. To estimate a portion of the indirect use benefits from reducing impingement and entrainment losses to forage species, EPA used a trophic transfer model that translates changes in impingement and entrainment losses of forage fish into changes in the harvest of commercial and recreational species that are subject to impingement and entrainment (*i.e.*, not the whole food web). This method is described in Chapter A1 of Part A of the *Regional Analysis Document*.

Stated preference methods, or benefit transfer based on stated preference studies, are the generally accepted techniques for estimating non-use values.

Stated preference methods rely on carefully designed surveys, which ask people either to state their willingness to pay for particular ecological improvements, such as increased protection of aquatic species or habitats with particular attributes; or to choose between competing hypothetical ''packages'' of ecological improvements and household cost. In either case, analysis of survey responses allows estimation of values.

Economists generally consider non-use values more difficult to assess than use values for several reasons:

a. Non-use values are not associated with easily observable behavioral trails;

b. Non-use values may be held by both users and non-users of a resource, and non-users may be less familiar with particular services provided by affected resources;

c. The development of a defensible stated preference survey that meets the NOAA blue ribbon panel requirements is often a time and resource intensive process,[52] and

d. Even carefully designed surveys may be subject to certain biases associated with the hypothetical nature of survey responses (Mitchell and Carson 1989).

Reducing impingement and entrainment losses of fish and shellfish may result in both use and non-use benefits. Of the organisms which are anticipated to be protected by the proposed options for the section 316(b) regulation for Phase III facilities, approximately 3.3 percent will eventually be harvested by commercial and recreational fishers and therefore can be valued with direct use valuation techniques. Unharvested fish, which have no direct use value, represent 96.7 percent of the total loss. These unlanded fish include forage fish and the unlanded portion of the stock of harvested species. Because unlanded fish contribute to the yield of harvested fish, they have an indirect use value that is captured by the direct use value of the fish that are caught. However, this indirect use value represents only a portion of the total value of unlanded fish. In fact, society may value both landed and unlanded fish for reasons unrelated to their use value. Such non-use values include the value that people may hold simply for knowing these fish exist. While non-use values are difficult to quantify, EPA believes it is important to consider such values, particularly since 96.7 percent of impinged and entrained organisms have no direct use value.

EPA considered several approaches to quantifying non-use values for the

[51] The benefits analysis of the proposed options for potentially regulated Phase III facilities does not assess option value as a distinct component of value because it is increasingly recognized that option value ''cannot be a separate component of value'' (Freeman, 2003; p. 249).

[52] The NOAA blue ribbon panel provided an extensive set of guidelines for survey construction, administration, and analysis to ensure that ''* * * CV produces estimates reliable enough to be the starting point of a judicial process of damage assessment, including passive-use values [*i.e.* non-use values]'' (see FR 58:10 pp.4601–4614, 1993).

proposed rule, including a stated preference study and meta-analysis of surface water valuation studies. The Agency has begun exploring the development of a stated preference survey that would measure non-use benefits from reduced impingement and entrainment attributable to the proposed options for the section 316(b) regulation for Phase III facilities. Although this primary study effort could not be completed in time for the publication of the proposed regulation, EPA expects to complete the study in time to rely on its findings for the final regulation. A number of studies have found that meta-analysis has considerable promise in benefits transfer and that meta-analysis can produce more reliable results than other benefit transfer methods (Bergstrom and De Civita, 1999, DCN 6–3109; Florax *et al.*, 2002, pp. 117–135, DCN 7–5132). However, the usefulness of meta-analysis results is dependent on both the quality of the underlying studies and their applicability to the policy question at hand. Given the difficulties in estimating non-use benefits at the national level using benefit transfer methods and the small number of studies that have attempted to value fish losses, particularly those related to impingement and entrainment at cooling water intake sites, EPA has not included monetary measures of non-use values in the benefit analysis for the proposed options. Instead, the Agency analyzed potential non-use benefits of the proposed options qualitatively.

2. Timing of Benefits

Discounting is the economic conversion of future benefits and costs to their present values, accounting for the fact that individuals tend to value future outcomes less than comparable near-term outcomes. Discounting is important when the value of benefits (or costs) may vary from year to year and when the time profiles of benefits and costs are not the same. Discounting enables a consistent comparison of benefits to costs across time periods.

For the section 316(b) rulemaking, the difference in timing in costs and benefits arises from two sources. First, facilities are not expected to achieve compliance with the regulation until several years after its promulgation. Benefits are equal to zero from the promulgation of the rule (*i.e.*, beginning of 2007) until facilities reach compliance. Thus, EPA discounted the benefits from each facility by the number of years between the year in which the rule is promulgated and the year in which the facility complies. Since benefits were estimated on a regional basis, EPA estimated benefits from each facility by multiplying total regional benefits by the percentage of total regional flow that is attributable to each facility. EPA used current permit expiration information for model facilities to identify the projected year of compliance for each facility in the analysis.

The second difference in timing in costs and benefits arises from the fact that additional time will pass between implementation of best technology available and resulting increased fishery yields. This is because one or more years may pass between the time an organism is spared impingement and entrainment and the time of its ultimate harvest. For example, a larval fish spared from entrainment (in effect, at age 0) may be caught by a recreational angler at age 3, meaning that a 3-year time lag arises between the installation of best technology available and the realization of the estimated recreational benefit. Likewise, if a 1-year old fish is spared from impingement and is then harvested by a commercial fisherman at age 2, there is a 1-year lag between the installation of best technology available and the subsequent commercial fishery benefit.

Recognizing that avoided fish deaths occur mainly in fish that are younger than harvestable age (eggs, larvae and juveniles), and that the benefits from avoided impingement and entrainment of these fish would be realized typically 3–4 years after their avoided death, EPA developed a benefits recognition schedule for facilities in each region. The benefits schedule is based on an estimate of benefit delay that reflects the estimated age and species composition of impingement and entrainment losses, by region. Following achievement of compliance, benefits from facilities in most regions are assumed to increase over a 7-year period to a long-term, steady State average, equal to the approximated per-facility benefit value discussed above, according to a numerical profile of < 0.0, 0.1, 0.2, 0.8, 0.9, 0.95, 1.0 >. This profile indicates the fraction of the steady State benefit value that is realized in each of the first seven years following the achievement of compliance at a facility. After seven years, this fraction remains 1.0 for 23 additional years. After these combined 30 years the facility is assumed to cease compliance, which is consistent with the time period over which costs are evaluated. In the same way that the benefits profile builds up over time following compliance, the benefits profile declines at the end of the compliance period. Specifically, in the seven years following the end of compliance, the fraction of the steady State benefit value achieved follows the profile of < 1.0, 0.9, 0.8, 0.2, 0.1, 0.05, 0.0 >. Therefore, the analysis of benefits encompasses a 37-year period starting with the first year of compliance. There are 35 years when benefits do not equal zero for a facility; 25 years when benefits are 100%; 10 years when benefits are a percentage of the total. These profile values are approximations based on a review of the age-specific fishing mortality rates that were used in the impingement and entrainment analysis and best professional judgment. Although EPA believes this approach is sufficient for this analysis, EPA could potentially refine these profile values through the use of a population model and will consider the feasibility of doing so.

For regions with a relatively high contribution of impingement to total impingement and entrainment (Inland, Great Lakes, and the Gulf of Mexico regions), EPA used an adjusted benefits profile of < 0.1, 0.2, 0.8, 0.9, 0.95, 1.0 >. This adjusted profile reflects that impinged fish are usually larger and older than entrained fish and thus benefits will be realized sooner in these regions.

EPA used these profiles of benefits to calculate a total present value of benefits and then to calculate a constant annual equivalent value (annualized value) of the present value. EPA performed the calculations of present value and annualized value using two discount rate values: a rate of 3% and a rate of 7%. As described above, the time profile of benefits, and therefore the discounting analysis, varies by facility. For all facilities, the first year of the analysis is 2007 (the promulgation of the rule). However, the first year in which benefits are realized varies by facility. Following this year, as outlined above, benefits increase over a six-or seven-year period, remain constant until the 30th year, and then decline over a six-or seven-year period. For a detailed discussion of the discounting methodology, refer to Chapter A8, ''Discounting Benefits'' and for a discussion of the time line of benefits, refer to Chapter H1, ''Total National Benefits'' in the *Regional Analysis Document* (DCN 7–0003).

3. Recreational Fishing Valuation

The recreational fishing benefits of the proposed options for the section 316(b) rule for Phase III facilities were estimated for six study regions (North Atlantic, Mid-Atlantic, Gulf of Mexico, California, Great Lakes, Inland) based on similarities in the affected ecosystems, aquatic species present, and characteristics of recreational fishing

activities within each of the six regions. To estimate recreational benefits of the proposed options for Phase III facilities, EPA developed a benefit transfer approach based on a meta-analysis of recreational fishing valuation studies designed to measure the various factors that determine willingness-to-pay for catching an additional fish per trip. To validate the meta-analysis results, EPA also used regional models of recreational fishing behavior developed for the Phase II analysis (DCN 6–0003) to estimate benefits from reduced impingement and entrainment at potentially regulated Phase III facilities for the four coastal regions and the Great Lakes region.[53]

a. Valuation Methods for Recreational Fishing

As the first step in its recreational fishing analysis, EPA conducted a comprehensive review of recreational fishing valuation literature to identify prior estimates of recreational use benefits that may be applicable to the section 316(b) regulation. Based on this review, EPA identified 48 studies that use established economic estimation techniques to measure the value of changes in marine or freshwater recreational catch (DCN 7–0003). All of these studies provide estimates of the marginal value to fishermen of catching an additional fish, or provide enough information for EPA to calculate such a value.

To examine the relative influence of methodology, sample, and fishery characteristics on the marginal value of catching an additional fish, EPA conducted a regression-based meta-analysis of these 48 studies. Although the valuation studies include estimates for a large number of different species, for the purposes of the model these species were aggregated into groups of similar species, including four saltwater species groups (big game, small game, flatfish, and other saltwater), two anadromous species groups (salmon and steelhead trout), and six freshwater species groups (panfish, bass, walleye/pike, muskellunge, rainbow trout, and other trout). The other saltwater group includes bottom fish species, species caught by anglers not targeting any particular species, and species that did not clearly fit in one of the other groups. The panfish group includes freshwater species such as yellow perch, catfish, and other warm water species. For the meta-analysis, some species groups were modeled interactively with regional variables to allow for variation in species value across different geographic regions.

The regression results from this analysis reveal both statistically significant and intuitively correct patterns in the way that factors influence the value to fishermen of catching an additional fish. These results allow for calculation of the marginal value per fish for different species based on resource and policy context characteristics. Additional detail on the methods EPA used in this analysis can be found in Chapter A5 of the *Regional Analysis Document.*

b. Validating the Recreational Analysis Based on the Region-Specific RUM Models

EPA also analyzed recreational fishing benefits from reduced impingement and entrainment based on region-specific random utility models (RUM) of recreational anglers' behavior for the four coastal regions and the Great Lakes region. These models were initially developed by the Agency for analysis of the final section 316(b) regulation for Phase II facilities.[54] For that regulation, EPA developed original RUM models for three of the four coastal regions (California, the Mid-Atlantic, and the Gulf of Mexico) and the Great Lakes region. For the North Atlantic region, EPA used a model developed by the National Marine Fisheries Service (NMFS) by Hicks *et al.* (Hicks, Steinback, Gautam, and Thunberg, 1999. Volume II: The Economic Value of New England and Mid-Atlantic Sportfishing in 1994—DCN 5–1271). Chapter A11 of the Phase II *Regional Analysis Document* provide more detailed discussion of the methodology used in EPA's RUM analysis (DCN 7–0003).

The regional recreational fishing studies used information on recreational anglers' behavior to infer anglers' economic value for the quality of fishing in the case study areas. The models' main assumption is that anglers will get greater satisfaction, and thus greater economic value, from sites where the catch rate is higher due to reduced impingement and entrainment, all else being equal. This benefit may occur in two ways: first, an angler may get greater enjoyment from a given fishing trip when catch rates are higher, and thus get a greater value per trip; second, anglers may take more fishing trips when catch rates are higher, resulting in greater overall value for fishing in the region. EPA modeled an angler's decision to visit a site as a function of site-specific cost, fishing trip quality, and additional site attributes such as presence of boat launching facilities or fish stocking at the site.

The Agency used 5-year historical catch rates per hour of fishing as a measure of baseline fishing quality in the regional studies. Catch rate is a policy variable of concern because catch rate is a function of fish abundance, which is affected by fish mortality caused by impingement and entrainment.

The Agency used the estimated model coefficients in conjunction with the estimated changes in impingement and entrainment in a given region to estimate per-day welfare gain to recreational anglers due to the proposed regulatory options for Phase III facilities. For the North Atlantic region, EPA used model coefficients estimated by Hicks *et al.* (1999) (DCN 5–1271).

To estimate the total economic value to recreational anglers for changes in catch rates resulting from changes in impingement and entrainment in a given region, EPA multiplied the total number of fishing days for a given region by the estimated per-day welfare gain due to the regulation. EPA estimated that the proposed regulatory options for Phase III facilities would cause only negligible changes in recreational fishing participation due to the improved quality of the fishing sites. Therefore, the welfare estimates for the four coastal regions and the Great Lakes are based on estimates of baseline recreational fishing participation provided by NOAA Fisheries and the Fish and Wildlife Service's *Annual Survey of Fishing, Hunting, and Wildlife-Related Recreation* (U.S. Department of the Interior, 2001, DCN 6–3231).

Results of the RUM models are presented in Chapter B4 through F4 of the *Regional Analysis Document.* In general, the RUM-based results fall within the range of values estimated based on the meta-model.[55] That the values from the two independent analyses are relatively close corroborates the use of meta-analysis in

[53] No RUM model was generated in the Phase II analysis for the Inland region because of a lack of data for that region so we could not verify the meta-analysis results for the Inland region.

[54] The RUM models for the North Atlantic, Mid-Atlantic, Gulf of Mexico, and California have not changed from the Phase II analysis. The Great Lakes RUM model was slightly refined for the Phase III analysis. The main differences between the Phase III and Phase II models include: (1) The ability to estimate separate values for yellow perch and bass and (2) the inclusion of site amenity effects in the site choice model (Besedin *et al.*, 2004: DCN 7–5000).

[55] The RUM models produced lower estimated recreational benefits in the Gulf of Mexico, Mid-Atlantic, and California regions, and higher estimates in the Great Lakes and North Atlantic regions. But no RUM estimates were outside of the lower and upper bound meta analysis values computed using the Krinksy and Robb approach.

estimating the value of incremental recreational fishing improvments resulting from the proposed section 316(b) regulation for Phase III facilities.

c. Application of the Meta-Analysis Results to the Analysis of Recreational Benefits of the Proposed 316(b) Rule

This section briefly discusses the use of the meta-analysis results to estimate the recreational benefits of the regulatory options evaluated for the proposed rule. Additional detail on this analysis, including EPA's treatment of uncertainty in per fish values, can be found in the *Regional Analysis Document* in Chapter A5. EPA began by calculating per fish values from the meta-analysis regression coefficients, based on regional and species specific values of the input variables. Because estimates from regression meta-models are subject to uncertainty, EPA used the Krinksy and Robb approach to estimate lower and upper bound marginal values for each species (DCN 6–3160). EPA also conducted a sensitivity analysis to determine how per fish values could change based on different selections for the independent variables. The per fish values and bounds used in this analysis of the recreational benefits of the regulatory options are based on EPA's best estimates of values for independent variables. The resulting per fish values are presented in Exhibit IX–6.

EXHIBIT IX–6.—ESTIMATED MARGINAL VALUE PER FISH TO RECREATIONAL ANGLERS

Region	Marginal value per fish caught, by region: saltwater fish [a] (June 2003 $)					
	Small game	Flatfish	Other saltwater [b]			
California	$12.57	$15.61	$4.52			
North Atlantic	7.64	8.06	4.20			
Mid-Atlantic	6.87	6.91	3.73			
Gulf of Mexico	5.32	.....	2.88			
Region	**Marginal value per fish caught, by region: freshwater fish [a] (June 2003 $)**					
	Small game [c]	Walleye/ Pike	Bass	Panfish	Salmon	Trout [d]
Great Lakes		$4.58	$5.90	$1.06	$11.19	$7.99
Inland	$7.38	5.15	6.96	0.97	.....	2.79

[a] Marginal values per fish are presented only for species in regions in which they are affected by one of the regulatory options evaluated for the proposed rule.
[b] Other saltwater species include bottom fish and other miscellaneous species.
[c] Anadromous species such as striped bass and American shad can be found in freshwater coastal rivers as well as in saltwater.
[d] The trout category includes all trout species except rainbow trout and lake trout.

To estimate the benefits of the alternative regulatory options, EPA multiplied the per fish values from Exhibit IX–6 by the number of additional fish that would be caught by anglers under each regulatory option due to reductions in impingement and entrainment, compared to current levels of recreational catch. Exhibits IX–7, IX–8, and IX–9 present the results of these calculations for the ''50 MGD for All Waterbodies,'' ''200 MGD for All Waterbodies,'' and ''100 MGD for Certain Waterbodies'' options. The proportion of impingement and entrainment losses of fishery species that were valued as lost recreational catch was determined from stock-specific fishing mortality rates, which indicate the fraction of a stock that is harvested by recreational anglers. Because fishing mortality rates are typically less than 20 percent, a proportion of the losses of fishery species were not valued in the recreational benefits analysis.

Exhibit IX–7 shows the annual increase in total recreational catch and resulting monetized benefits resulting from the ''50 MGD for All Waterbodies'' option. The exhibit shows that compared to the current national level of recreational catch, anglers would catch 620,000 additional fish per year under this option, resulting in total undiscounted benefits of $2.12 million per year. The annualized value of these additional fish is $1.77 million and $1.39 million, evaluated at 3 percent and 7 percent discount rates, respectively. Increased recreational catch is largest in the Gulf of Mexico region, where the rule would increase annual recreational catch by 183,000 fish, resulting in an undiscounted recreational welfare gain of $0.67 million.

Exhibit IX–7 also presents lower and upper confidence bounds for the benefits of the ''50 MGD for All Waterbodies'' option. These bounds are based on using the Krinsky and Robb technique to estimate the 95th and 5th confidence limits on the marginal value per fish predicted by the meta-analysis. Undiscounted national benefits of this option range from $1.02 million to $4.47 million per year, and benefits in the Gulf of Mexico region range from $0.30 million to $1.50 million per year, based on 90 percent confidence limits on the marginal value per fish predicted by the meta-analysis.

EXHIBIT IX–7.—RECREATIONAL BENEFITS UNDER THE ''50 MGD FOR ALL WATERBODIES'' OPTION

Region	Increase in annual recreational catch compared to current recreational catch (thousands of fish)	Annualized benefits (thousands, 2003 $) [a]		
		Low	Mean	High
California	5	$12	$28	$66

EXHIBIT IX–7.—RECREATIONAL BENEFITS UNDER THE ''50 MGD FOR ALL WATERBODIES'' OPTION—Continued

Region	Increase in annual recreational catch compared to current recreational catch (thousands of fish)	Annualized benefits (thousands, 2003 $) [a]		
		Low	Mean	High
North Atlantic	13	36	77	169
Mid-Atlantic	159	290	612	1,301
Gulf of Mexico	183	298	667	1,499
Great Lakes	92	192	385	756
Inland	167	189	358	675
National total (undiscounted) [b]	620	1,016	2,127	4,466
National total (evaluated at 3%) [c]	620	843	1,765	3,704
National total (evaluated at 7%) [c]	620	665	1,391	2,919

[a] Lower and upper bounds are calculated using the Krinsky and Robb technique to estimate the 95th and 5th percentile limits on the marginal value per fish predicted by the meta-analysis.
[b] Undiscounted benefits are calculated from the annual increase in recreational catch, evaluated at a steady State condition. All regional results presented in this table are undiscounted. Undiscounted benefits are not directly comparable to cost.
[c] Annualized benefits represent the value of all recreational benefits generated over the time frame of the analysis, discounted to 2007, and then annualized over a thirty year period. For a more detailed discussion of the discounting methodology, refer to section IX.D.2 of this preamble.

Exhibit IX–8 shows the annual increase in recreational catch and resulting monetized benefits resulting from the ''200 MGD for All Waterbodies'' option. The exhibit shows that compared to the current national level of recreational catch, anglers would catch 419,000 additional fish per year under this option, resulting in total undiscounted benefits of $1.43 million per year. The annualized value of these additional fish is $1.18 million and $0.92 million, evaluated at 3 percent and 7 percent, respectively. Increased recreational catch is largest in the Mid-Atlantic region, where this option would increase annual recreational catch by 141,000 fish, resulting in an undiscounted welfare gain of $0.55 million.

The exhibit also presents lower and upper confidence bounds for the benefits of the ''200 MGD for All Waterbodies'' option. Undiscounted national benefits of this option range from $0.69 million to $2.99 million per year, and benefits in the Mid-Atlantic region range from $0.26 million to $1.16 million per year, based on 90 percent confidence limits on the marginal value per fish predicted by the meta-analysis.

EXHIBIT IX–8.—RECREATIONAL BENEFITS UNDER THE ''200 MGD FOR ALL WATERBODIES'' OPTION

Region	Increase in annual recreational catch compared to current recreational catch (thousands of fish)	Annualized benefits (thousands, 2003 $) [a]		
		Low	Mean	High
California	0	$0	$0	$0
North Atlantic	3	8	16	36
Mid-Atlantic	141	258	545	1,158
Gulf of Mexico	100	163	364	819
Great Lakes	64	132	266	523
Inland	111	128	242	456
National total (undiscounted) [b]	419	689	1,434	2,991
National total (evaluated at 3%) [c]	419	567	1,181	2,463
National total (evaluated at 7%) [c]	419	443	922	1,922

[a] Lower and upper bounds are calculated using the Krinsky and Robb technique to estimate the 95th and 5th percentile limits on the marginal value per fish predicted by the meta-analysis.
[b] Undiscounted benefits are calculated from the annual increase in recreational catch, evaluated at a steady State condition. All regional results presented in this table are undiscounted. Undiscounted benefits are not directly comparable to cost.
[c] Annualized benefits represent the value of all recreational benefits generated over the time frame of the analysis, discounted to 2007, and then annualized over a thirty year period. For a more detailed discussion of the discounting methodology, refer to section IX.D.2 of this preamble.

Exhibit IX–9 shows the annual increase in recreational catch and resulting monetized benefits resulting from the ''100 MGD for Certain Waterbodies'' option. The exhibit shows that compared to the current national level of recreational catch, anglers would catch 407,000 additional fish per year under this option, resulting in total undiscounted benefits of $1.57 million per year. The annualized value of these additional fish is $1.29 million and $1.01 million, evaluated at 3 percent and 7 percent, respectively. Increased recreational catch is largest in the Gulf of Mexico, where this option would increase annual recreational catch by 183,000 fish, resulting in an

undiscounted welfare gain of $0.67 million.

The exhibit also presents lower and upper confidence bounds for the benefits of the ''100 MGD for Certain Waterbodies'' option. Undiscounted national benefits of this option range from $0.73 million to $3.38 million per year, and benefits in the Gulf of Mexico region range from $0.30 million to $1.50 million per year, based on 90 percent confidence limits on the marginal value per fish predicted by the meta-analysis.

EXHIBIT IX–9.—RECREATIONAL BENEFITS UNDER THE ''100 MGD FOR CERTAIN WATERBODIES'' OPTION

Region	Increase in annual recreational catch compared to current recreational catch (thousands of fish)	Annualized benefits (thousands, 2003 $) [a]		
		Low	Mean	High
California	0	$0	$0	$0
North Atlantic	11	29	63	137
Mid-Atlantic	141	258	545	1,158
Gulf of Mexico	183	298	667	1,499
Great Lakes	72	148	299	586
Inland	0	0	0	0
National total (undiscounted) [b]	407	733	1,573	3,380
National total (evaluated at 3%) [c]	407	602	1,292	2,779
National total (evaluated at 7%) [c]	407	468	1,006	2,164

[a] Lower and upper bounds are calculated using the Krinsky and Robb technique to estimate the 95th and 5th percentile limits on the marginal value per fish predicted by the meta-analysis.

[b] Undiscounted benefits are calculated from the annual increase in recreational catch, evaluated at a steady State condition. All regional results presented in this table are undiscounted. Undiscounted benefits are not directly comparable to cost.

[c] Annualized benefits represent the value of all recreational benefits generated over the time frame of the analysis, discounted to 2007, and then annualized over a thirty year period. For a more detailed discussion of the discounting methodology, refer to section IX.D.2 of this preamble.

d. Limits and Uncertainties

Benefit transfers by definition are characterized by a difference between the context in which resource values are estimated and that in which benefit estimates are desired. The ability of meta-analysis to adjust for the influence of study, economic, and resource characteristics on recreational values can minimize, but not eliminate, potential biases. The meta-analysis model presented here provides a close but not perfect match to the context in which values are desired. Some of the key limitations inherent to the meta-model and the subsequent benefit transfer are the following:

A. The per fish values estimated from the model depend on the values of the input variables in the meta-analysis. EPA assigned values to the input variables based on established economic theory and characteristics of the affected species and regions. However, because the input values for some variables are uncertain, the resulting per fish values and benefits estimates are also uncertain.

B. As mentioned above, the economic and resource characteristics of the 48 studies used in the meta-analysis are not perfectly matched to the economic and resource characteristics of sites affected by the regulatory options evaluated for the proposed rule. In particular, although most of the Inland studies take place in the Great Lakes region, the regulatory options affect sites all across the Inland region. However, EPA believes that regional differences in per fish values for specific Inland species are relatively small.

C. By aggregating species into categories, EPA was able to improve the fit of the meta-analysis model. However, this aggregation results in a lower level of detail in the values that can be predicted. In particular, the panfish category and other saltwater category include relatively diverse species.

D. Projected changes in recreational catch may be overestimated because potential compensatory effects in affected species' reproduction or survival rates were not taken into account.

E. In estimating recreational fishery losses, EPA used impingement and entrainment data provided by the facilities. While EPA used the most current data available, in some cases these data are 20 years old or older. Thus, they may not reflect current conditions. Also, data from Phase II facilities may not be representative of Phase III facilities.

F. Impingement and entrainment estimates include only individuals directly lost to impingement and entrainment, not their progeny, and may therefore be underestimates.

G. In estimating the benefits of improved recreational angling, the Agency only assigned a monetary benefit to the increases in consumer surplus for the baseline number of fishing days. Thus, benefits will be understated if participation increases in response to increased availability of fishery species as a result of reduced impingement and entrainment. This approach omits the portion of recreational fishing benefits that arise when improved conditions lead to higher levels of participation. Empirical evidence suggests that the omission of increased angling days can lead to an underestimate of total recreational fishing benefits. However, the magnitude of this error is likely to be small.

4. Commercial Fishing Valuation

Reductions in impingement and entrainment at cooling water intake structures are expected to benefit the commercial fishing industry. The effect is straightforward: Reducing the number of fish killed will probably increase the number of fish available for harvest. Measuring the benefits of this effect is less straightforward. This section presents the methods EPA used to estimate commercial benefits, as well as the resulting benefits estimates.

a. Methods

EPA estimated commercial benefits by first estimating the value of total losses under current impingement and entrainment conditions (or the total

benefits of eliminating all impingement and entrainment). Then, based on review of the empirical literature, EPA assumed that producer surplus is equal to 40 percent of baseline losses. Finally, EPA estimated benefits under different options for the proposed section 316(b) rule for Phase III facilities by applying the estimated percentage reduction in impingement and entrainment to the estimated producer surplus to obtain the estimated increase in producer surplus attributable to the option. This methodology was applied in each region except the Inland region (which does not include any significant commercial fishing). See Chapter A4 of the *Regional Analysis Document* for details about EPA's methodology.

To determine regional losses and benefits, EPA conducted several analyses. EPA estimated losses to commercial harvest (in pounds of fish) attributable to impingement and entrainment under current conditions by modeling these fish losses by applying a linear stock-to-harvest assumption (*i.e.*, a 10 percent change in the stock would result in a 10 percent change in harvest). The percentage of fish harvested is based on data on historical fishing mortality rates. EPA estimated gross revenue of lost commercial catch (*i.e.*, the increase in gross revenue that would be expected if all current impingement and entrainment were eliminated) by using landings and dockside prices ($/lb) as reported by the NOAA Fisheries for the period 1991–2001. The conceptually suitable measure of benefits is the sum of any changes in producer and consumer surplus. The methods used for estimating the change in surplus depend on whether the physical impact on the commercial fishery market appears sufficiently small such that it is reasonable to assume there will be no appreciable price changes in the markets for the impacted fisheries.

For the regions and magnitude of losses included in this analysis, it is reasonable to assume no change in price, which implies that the welfare change is limited to changes in producer surplus. This change in producer surplus is assumed to be equivalent to a portion of the change in gross revenues. EPA assumes a range of 0 percent to 40 percent of the estimated gross revenue losses as a means of estimating the change in producer surplus. This is based on a review of empirical literature and is consistent with recommendations made in comments on the Phase II proposal.

EPA believes this is a reasonable approach to estimating producer surplus when there are no anticipated price changes. EPA's (2000) Guidelines for Preparing Economic Analyses (EPA 240–R–00–003) describes options for estimating ecological benefits for fisheries, and notes that ''if changes in service flows are small, current market prices can be used as a proxy for expected benefit * * * a change in the commercial fish catch might be valued using the market price for the affected species.'' In EPA's review of the commercial fishing literature two alterative methods for computing producer surplus as a percentage of gross revenues also came to the fore. The more common approach to calculating benefits relies on estimating normal profit as a percentage of gross revenue. In the surveyed studies this percentage of gross review ranges from -5 percent to 91.2 percent. The second approach to estimating commercial benefits, which may produce the more appropriate measure of welfare, computes the producer surplus as a percentage of gross revenue. The studies that use this method return percentages that range from 0 to 37, due to reduced profit estimates that include a return to the owners as part of costs. In light of these findings EPA has chosen to use 0 percent to 40 percent as the estimated range of percent of gross revenue that best captures the additional benefit that will accrue to commercial fishers.

Once the commercial surplus losses associated with impingement and entrainment under baseline conditions have been estimated, EPA estimates the percentage reduction in impingement and entrainment at each facility under each regulatory option. This analysis is conducted for each region.

b. Results

Exhibit IX–10 presents the estimated annualized commercial fishing benefits attributable to three co-proposed options: The ''50 MGD for All Waterbodies'' option (50 MGD All); the ''200 MGD for All Waterbodies'' option (200 MGD All); and the ''100 MGD for Certain Waterbodies'' option (100 MGD oceans, estuaries, tidal rivers, or one of the Great Lakes). The results reported include the total reduction in losses in pounds of fish and the value of this reduction discounted at 0 percent, 3 percent, and 7 percent. Total annualized commercial fishing benefits, applying a 3 percent discount rate, are estimated to be $0 to $132,000 per year for the 50 MGD option, $0 to $79,000 per year for the 200 MGD option, and $0 to $118,000 per year for the 100 MGD for certain waterbodies option. When a 7 percent discount rate is applied, the total annualized commercial fishing benefits for the 50 MGD option are estimated to be $0 to $104,000, under the 200 MGD option benefits equal $0 to $79,000, and for the 100 MGD for certain waterbodies option the discounted benefits are $0 to $93,000.

EXHIBIT IX–10.—ANNUALIZED COMMERCIAL FISHING BENEFITS FOR IMPINGED AND ENTRAINED FISH EXPECTED UNDER THE CO-PROPOSED OPTIONS [a]

Region [b]	Reduction in lost yield (thousands of lbs)			Benefits (thousands; $ 2003) [c d]		
	50 MGD all	200 MGD all	100 MGD certain waterbodies	50 MGD all	200 MGD all	100 MGD certain waterbodies
California	16	0	0	$6	$0	$0
North Atlantic	8	2	6	4	1	3
Mid-Atlantic	459	408	408	31	27	27
Gulf of Mexico	313	171	313	93	51	93
Great Lakes	86	59	66	25	17	19
National total, [e] (undiscounted)	882	640	794	159	96	143
National total, (evaluated at 3%)	882	640	794	132	79	118
National total, (evaluated at 7%)	882	640	794	104	62	93

[a] Benefits are upper bound benefits based on 40% of gross revenue. The lower bound is $0.
[b] No significant commercial fishing takes place in the Inland region, and thus this region is excluded from this analysis.
[c] Discounted to account for lag in implementation and lag in time required for fish lost to I&E to reach a harvestable age.

[d] Annualized benefits represent the value of all commercial benefits generated over the time frame of the analysis, discounted to 2007, and then annualized over a thirty year period. For a more detailed discussion of the discounting methodology, refer to Section IX.D.2 of this preamble.
[e] Undiscounted benefits are not comparable to costs.

c. Limitations and Uncertainties

Some of the major uncertainties and assumptions of EPA's commercial fishing analysis include:

A. The analysis only includes individuals that are directly killed by impingement and entrainment, not their progeny and may therefore underestimate projected changes in harvest.

B. Projected changes in commercial catch may be overestimated because potential compensatory effects in affected species' reproduction or survival rates were not taken into account.

C. Projected changes in harvest may be too high or too low because interactions with other stressors are not considered.

D. EPA used impingement and entrainment data provided by the facilities. While EPA used the most current data available, in some cases these data are 20 years old or older. Thus, they may not reflect current conditions. Also data from Phase II facilities may not be representative of Phase III facilities.

E. EPA assumes a linear stock to harvest relationship (*i.e.*, a 10 percent change in stock would have a 10 percent change in landings); this may be low or high, depending on the condition of the stocks. Region-specific fisheries regulations also will affect the validity of the linear assumption.

F. EPA assumes that NOAA Fisheries landings data are accurate and complete. However, in some cases prices and/or quantities may be reported incorrectly.

G. EPA currently estimates that the increase in producer surplus as a result of the rule will be between 0 percent and 40 percent of the estimated change in gross revenues. The research used to develop this range is not region-specific; thus the true value may fall outside this range for some regions and species.

5. Non-Use Benefits

To assess public policy significance or importance of the ecological gains from the proposed regulation for Phase III facilities, EPA developed the relevant information and considered non-use benefits of the proposed options qualitatively. This assessment is discussed below.

a. Qualitative Assessment

EPA is able to assign direct use value to only a very small fraction of the fish lost to impingement and entrainment. As shown in Exhibit IX–11, fish with a direct use value, which include only those fish that are harvested, account for only 3.3 percent of the total age-1 equivalent impingement and entrainment loss. Unharvested fish (*i.e.*, forage fish and the unlanded portion of the stock of harvested species), which have no direct use value, represent 96.7 percent of the total loss. A portion of the total benefits of these unharvested commercial, recreational, and forage species, can be derived indirectly from the estimated use values of the harvested animals. As noted in section IX.D.1, society may value both landed and unlanded fish for reasons unrelated to their use value. Such non-use values include the value that people may hold simply for knowing these fish exist. EPA believes it is important to consider such values, at least qualitatively, particularly since such a large percentage of impinged and entrained organisms have no direct use value.

EXHIBIT IX–11.—NUMBER AND PERCENTAGE OF BASELINE IMPINGEMENT AND ENTRAINMENT LOSSES BY SPECIES CATEGORY

Region	Age-1 adult equivalents (millions)				
	All species	Forage species	Commercial and recreational species	Harvested commercial and recreational species	I&E of harvested species as percentage of total I&E
California	1.31	0.666	0.642	0.0594	4.54
North Atlantic	2.34	1.77	0.572	0.0542	2.32
Mid-Atlantic	23.2	14.8	8.47	1.46	6.29
South Atlantic	1.52	0.78	0.74	.011	7.41
Gulf of Mexico	12.7	3.71	9.01	1.2	9.43
Great Lakes	34.4	32.8	1.54	0.543	1.58
Inland	44.2	35.6	8.6	0.511	1.15
National total[a]	120	90.2	29.6	3.94	3.29

[a] The national total includes baseline impingement and entrainment losses at four sample-weighted potentially regulated facilities in the South Atlantic region.

Changes in cooling water intake system design or operations resulting from the proposed section 316(b) regulations for Phase III facilities are expected to reduce impingement and entrainment losses of fish, shellfish, and other aquatic organisms and, as a result, are expected to increase the numbers of individuals present and benefit local and regional fishery populations. Depending on the nature and magnitude of the reduced losses and of conditions at a given site, this may ultimately contribute to the enhanced environmental functioning of affected waterbodies (rivers, lakes, estuaries, and oceans) and associated ecosystems. EPA does not have the data to determine whether reducing impingement and entrainment losses at Phase III facilities will have significant ecological benefits. However, the discussion that follows describes benefits that may result from reducing impingement and entrainment losses generally.

EPA believes that reducing fish mortality from impingement and

entrainment would contribute to the health and sustainability of the affected fish populations by reducing the overall level of mortality for those populations. Fish populations suffer from numerous sources of mortality; some are natural and others are anthropogenic. Natural sources include weather, predation by other fish, and the availability of food. Human impacts that affect fish populations include fishing, pollution, habitat changes, and impingement and entrainment losses at cooling water intake structures. Fish populations decline when they are unable to sufficiently compensate for their overall level of mortality. Lowering the overall mortality level increases the probability that a population will be able to compensate for mortality at a level sufficient to maintain the long-term health of the population.

In addition to their importance in providing food and other goods of direct use to humans, the organisms lost to impingement and entrainment may be critical to the continued functioning of the ecosystems of which they are a part depending on the magnitude of the actual impingement and mortality losses attributable to Phase III facilities. The discussion that follows describes the kinds of impacts that EPA believes may be due to impingement mortality and entrainment losses generally, not necessarily those at Phase III facilities. Fish are essential for energy transfer in aquatic food webs, regulation of food web structure, nutrient cycling, maintenance of sediment processes, redistribution of bottom substrates, the regulation of carbon fluxes from water to the atmosphere, and the maintenance of aquatic biodiversity (Peterson and Lubchenco, 1997; Postel and Carpenter, 1997; Holmlund and Hammer, 1999; Wilson and Carpenter, 1999). Examples of impacts on ecological conditions, functions and services that may result from impingement and entrainment include: (1) Decreased numbers of ecological keystone, rare, sensitive, or threatened and endangered species; (2) decreased numbers of popular commercial and recreational fish species that are not fished, perhaps because the fishery is closed; (3) increased numbers of exotic or disruptive species that compete well in the absence of species lost to impingement and entrainment (impingement and entrainment may also help remove some exotic or disruptive organisms); (4) disruption of ecological niches and ecological strategies used by aquatic species; (5) disruption of energy transfer through the food web; (6) decreased local biodiversity; (7) disruption of predator-prey relationships; (8) disruption of age class structures of species; (9) disruption of natural succession processes. Many of these functions and services can only be maintained by the continued presence of all life stages of fish and other aquatic species in their natural habitats. While some ecological services of aquatic species have been studied, other ecosystems services, relationships, and interrelationships are unknown or poorly understood. To the extent that the latter are not captured in the benefits analyses, total benefits may be underestimated.

Scientific and public interest in protecting ecosystem services is increasing with the recognition that these services are vulnerable to a wide range of human activities and are difficult, if not impossible, to replace with human technologies (Meffe, 1992; DCN 7–5250). Reducing impingement and entrainment losses could contribute to restoring (or preserving) the biological integrity of the ecosystems of substantial national importance.

In the 1987 amendments to the CWA, Congress established the National Estuary Program because the ''Nation's estuaries are of great importance to fish and wildlife resources and recreation and economic opportunity * * * [, and] maintaining the health and ecological integrity of these estuaries is in the national interest (Water Quality Act of 1987 (Pub. L. 100–4), § 317(a)(1)(A) and (B) adding § 320 to the CWA, 33 US.C. 1330). So far, there are 28 estuaries designated under the National Estuary Program (NEP). In addition, the largest estuary in the United States, Chesapeake Bay, is protected under its own Federally mandated program, separate but related to NEP. Of the 15 estuaries from which the potentially regulated Phase III facilities withdraw cooling water, 12 are nationally significant estuaries designated under NEP or the Chesapeake Bay Program.

Substantial Federal and State resources have been directed to NEP to enhance conservation and knowledge about the estuaries designated under this program. Since 1998, more than $95 million dollars has been devoted to NEP to benefit the health of the nationally significant estuaries (NEP, 2004, DCN 7–5125).

Reducing impingement and entrainment at potentially regulated Phase III facilities may also benefit freshwater ecosystems of national significance, including the Great Lakes Basin, Mississippi River, and Columbia River. These waterbodies are subject to large-scale ecosystem restoration efforts that are good indicators of great public interest in restoring the ecological health of these ecosystems (U.S. Fish and Wildlife Service, 2004, DCN 7–5126; U.S. Department of the Interior, 2004, DCN 7–5127; Northeast Midwest Institute, 2004, DCN 7–5128; The Upper Mississippi River Basin Association, 2004, DCN 7–5129). The ecosystem restoration efforts focus on many issues, including coastal habitat restoration, protection of fish species, conservation of migratory birds and endangered species. For example, between 1992 and 2001, more than $17 million was devoted to projects to restore and conserve the Great Lakes ecosystem, and $102 million was spent on improving the Mississippi River ecosystem (U.S. EPA, 2004, DCN 7–5130; and Brescia, 2002, DCN 7–5131). Reducing impingement and entrainment of aquatic organisms may improve the quality of aquatic habitat and contribute to improvement of the biological integrity and health of these ecosystems.

Finally, reducing impingement and entrainment in waterbodies that do not have national significance may contribute to restoration or protection of ecosystems of regional or local importance.

Today's proposed rule may also help preserve threatened and endangered species by reducing the number of individuals lost to impingement and entrainment. Threatened and endangered (T&E) and other special status species directly affected by impingement and entrainment include, pallid sturgeon, delta smelt, Sacramento splittail, and longfin smelt. Threatened and endangered species can also suffer indirect impacts if impingement and entrainment at cooling water intake structures disrupts their food source or their critical habitat. The loss of individuals of listed species from impingement and entrainment is particularly important because, by definition, these species are already rare and at risk of irreversible decline because of other stressors. EPA explored several methods for valuing reductions in threatened and endangered species losses. However, EPA has not included quantitative measures of non-use values associated with protection of threatened and endangered species in the proposed section 316(b) rule for Phase III facilities benefit analysis due to current uncertainty about the extent of Phase III facilities' impact on threatened and endangered species at the national level and EPA's inability to monetize such benefits given the available economic valuation literature. Details about possible non-use benefits valuation approaches are presented in Chapter A9

of the 316(b) Regional Analysis Document (DCN 7–0003).

6. National Benefits

Quantifying and monetizing reduction in impingement and entrainment losses due to today's proposed rule is challenging, and the preceding sections discuss specific limitations and uncertainties associated with estimation of commercial, recreational, and non-use benefit categories. National benefit estimates are subject to uncertainties inherent in valuation approaches used for assessing the three benefits categories. The combined effect of these uncertainties is of unknown magnitude or direction (*i.e.*, the estimates may over or under state the anticipated national-level benefits); however, EPA has no data to indicate that the results for each benefit category are atypical or unreasonable. Since the Agency was unable to monetize non-use benefits, the estimates of total benefits reflect use values only.

Exhibit IX–13 presents EPA's estimates of the total monetized benefits from impingement and entrainment reduction under the ''50 MGD for All Waterbodies'' option. The annualized use benefits from impingement and entrainment reduction post regulation are $1.90 million per year (2003$), with lower and upper bounds of $0.98 million and $3.84 million, discounted at three percent. Discounted at seven percent, annualized use benefits are $1.50 million per year, with lower and upper bounds of $0.77 million and $3.02 million.

EXHIBIT IX–13.—SUMMARY OF MONETIZED SOCIAL BENEFITS ''50 MGD FOR ALL WATERBODIES'' OPTION

[Thousands; 2003 $] [a]

Region	Annualized commercial fishing benefits	Annualized recreational fishing benefits			Total annualized value of monetizable impingement and entrainment reductions [b]		
		Low	Mean	High	Low	Mean	High
Evaluated at a 3 percent discount rate							
California	$0–$5	$10	$24	$57	$16	$29	$62
North Atlantic	0–3	29	63	138	32	66	141
Mid-Atlantic	0–25	235	497	1,057	260	522	1,082
Gulf of Mexico	0–78	249	558	1,254	327	636	1,332
Great Lakes	0–20	157	316	621	178	337	641
Inland [c]	0	162	306	577	162	306	577
National total	0–132	843	1,765	3,704	975	1,897	3,836
Evaluated at a 7 percent discount rate							
California	0–4	9	20	47	13	24	51
North Atlantic	0–2	22	49	107	25	51	109
Mid-Atlantic	0–19	181	382	811	200	401	830
Gulf of Mexico	0–62	198	444	998	260	506	1,061
Great Lakes	0–16	122	246	483	138	262	499
Inland [c]	0	133	251	473	133	251	473
National total	0–104	665	1,391	2,919	769	1,495	3,023

[a] All benefits presented in this exhibit are annualized. These annualized benefits represent the value of all benefits generated over the time frame of the analysis, discounted to 2007, and then annualized over a thirty year period. For a more detailed discussion of the discounting methodology, refer to section IX.D.2 of this preamble.

[b] The total monetizable value of impingement and entrainment reductions includes use benefits only. EPA evaluated non-use benefits only qualitatively. A range of recreational fishing benefits is provided, based on the Krinsky and Robb technique to estimate the 95th and 5th percentile limits on the marginal value per fish predicted by the meta-analysis. Commercial fishing benefits are computed based on a range from 0 percent to 40 percent of the change in gross revenue, as explained in the text. To calculate the total monetizable value columns (low, mean, and high), the high end value for commercial fishing benefits is added to the low, medium and high values for recreational fishing benefits respectively.

[c] There are no commercial fishing benefits in the Inland region.

Exhibit IX–14 presents EPA's estimates of the total monetized benefits from impingement and entrainment reduction under the ''200 MGD for All Waterholes'' option. The annualized use benefits from impingement and entrainment reduction post regulation are $1.26 million per year (2003$), with lower and upper bounds of $0.65 million and $2.54 million, discounted at three percent. Discounted at seven percent, annualized use benefits are $0.98 million per year, with lower and upper bounds of $0.51 million and $1.98 million.

EXHIBIT IX–14.—SUMMARY OF MONETIZED SOCIAL BENEFITS ''200 MGD FOR ALL WATERBODIES'' OPTION

[Thousands; 2003 $] [a]

Region	Annualized commercial fishing benefits	Annualized recreational fishing benefits			Total annualized value of monetizable impingement and entrainment reductions [b]		
		Low	Mean	High	Low	Mean	High
Evaluated at a 3 percent discount rate							
California	$0	$0	$0	$0	$0	$0	$0
North Atlantic	0–1	6	13	28	7	14	29
Mid-Atlantic	0–22	208	440	934	230	462	956
Gulf of Mexico	0–43	136	305	685	179	347	728
Great Lakes	0–14	108	216	425	122	230	439
Inland [c]	0	110	207	390	110	207	390
National total	0–79	567	1,181	2,463	647	1,260	2,542
Evaluated at a 7 percent discount rate							
California	0	0	0	0	0	0	0
North Atlantic	0	4	10	21	5	10	21
Mid-Atlantic	0–17	158	334	709	175	350	726
Gulf of Mexico	0–34	108	243	545	142	277	579
Great Lakes	0–11	83	166	326	93	177	337
Inland [c]	0	90	170	321	90	170	321
National total	62	443	922	1,922	505	984	1,984

[a] All benefits presented in this exhibit are annualized. These annualized benefits represent the value of all benefits generated over the time frame of the analysis, discounted to 2007, and then annualized over a thirty year period. For a more detailed discussion of the discounting methodology, refer to section IX.D.2 of this preamble.
[b] The estimate of the total monetizable value of impingement and entrainment reductions includes use benefits only.
[c] There are no commercial fishing benefits in the Inland region.

Exhibit IX–15 presents EPA's estimates of the total monetized benefits from impingement and entrainment reduction under the ''100 MGD for Certain Waterbodies'' option. The annualized use benefits from impingement and entrainment reduction post regulation are $1.41 million per year (2003$), with lower and upper bounds of $0.72 million and $2.90 million, discounted at three percent. Discounted at seven percent, annualized use benefits are $1.10 million per year, with lower and upper bounds of $0.56 million and $2.26 million.

EXHIBIT IX–15.—SUMMARY OF MONETIZED SOCIAL BENEFITS ''100 MGD FOR CERTAIN WATERBODIES'' OPTION

[Thousands; 2003 $] [a]

Region	Annualized commercial fishing benefits	Annualized recreational fishing benefits			Total annualized value of monetizable impingement and entrainment reductions [b]		
		Low	Mean	High	Low	Mean	High
Evaluated at a 3 percent discount rate							
California	$0	$0	$0	$0	$0	$0	$0
North Atlantic	0–2	24	52	113	26	54	115
Mid-Atlantic	0–22	208	440	934	230	462	956
Gulf of Mexico	0–78	249	558	1,254	327	636	1,332
Great Lakes	0–16	121	243	478	137	259	494
Inland [c]	0	0	0	0	0	0	0
National total	0–118	602	1,292	2,779	720	1,411	2,897
Evaluated at a 7 percent discount rate							
California	0	0	0	0	0	0	0
North Atlantic	0–2	19	40	88	20	42	90
Mid-Atlantic	0–17	158	334	709	175	350	726
Gulf of Mexico	0–62	198	444	998	260	506	1,061
Great Lakes	0–12	93	188	368	105	200	381
Inland [c]	0	0	0	0	0	0	0

EXHIBIT IX–15.—SUMMARY OF MONETIZED SOCIAL BENEFITS ''100 MGD FOR CERTAIN WATERBODIES'' OPTION—Continued

[Thousands; 2003 $] [a]

Region	Annualized commercial fishing benefits	Annualized recreational fishing benefits			Total annualized value of monetizable impingement and entrainment reductions [b]		
		Low	Mean	High	Low	Mean	High
National total	0–93	468	1,006	2,164	561	1,099	2,257

[a] All benefits presented in this exhibit are annualized. These annualized benefits represent the value of all benefits generated over the time frame of the analysis, discounted to 2007, and then annualized over a thirty year period. For a more detailed discussion of the discounting methodology, refer to section IX.D.2 of this preamble.
[b] The estimate of the total monetizable value of impingement and entrainment reductions includes use benefits only.
[c] There are no commercial fishing benefits in the Inland region.

EPA considered a wide range of policy options in developing the proposed section 316(b) regulation for the Phase III facilities. The Regional Analysis Document provides EPA's complete benefit assessment for the alternative policy options considered in this rulemaking.

X. Comparison of Benefits and Costs

This section presents two measures that compare the benefits and costs of the regulatory options: (1) A benefit-cost analysis, and (2) a break-even analysis of the minimum non-use benefits required for total annualized benefits to equal total annualized costs, on a per household basis. Each measure is presented by study region.

A. Benefit-Cost Analysis

The benefit-cost analysis for each of the co-proposed regulatory options compares total annualized use benefits to total annualized pre-tax costs (social costs) at existing facilities that remain open in the baseline.[56] Benefits and costs were discounted using both a 3 percent and 7 percent discount rate. The cost estimates include costs of compliance to facilities subject to the proposed rule as well as administrative costs incurred by State and local governments and by the Federal government. The benefits estimates include monetized benefits to commercial and recreational fishing. The total monetizable benefits include only use benefits. The non-use benefits were evaluated qualitatively. Thus, the benefit-cost analysis compares a generally complete measure of social costs with an incomplete measure of social benefits and should be interpreted bearing in mind this inconsistency.

1. Benefit-Cost Analysis Results

Exhibit X–1 presents a summary of total annualized use benefits, total annualized costs, and net benefits for the ''50 MGD for All Waterbodies'' option. Under this option, 136 facilities (excluding baseline closures) are subject to the regulation. Of those facilities, it is assumed that 103 are required to install technologies to reduce impingement mortality and entrainment, and 32 will incur permitting costs only. The exhibit shows that the use benefits of the 50 MGD option are not projected to exceed the costs in any of the study regions. In the California region, costs exceed use benefits by $0.8 million or $0.9 million when discounted at 3 percent and 7 percent respectively. In the Inland region, costs are $19.4 million or $20.4 million greater than the use benefits. At the national level, EPA projects the costs of this option to exceed its use benefits by $45.4 million per year, discounted at 3 percent, or by $48.6 million per year, discounted at 7 percent.

EXHIBIT X–1.—SUMMARY OF SOCIAL BENEFITS AND COSTS ''50 MGD FOR ALL WATERBODIES'' OPTION

[Millions; $ 2003]

Study region	Number of facilities subject to option	Number of facilities installing technology	Total annualized use value of I&E reductions [a]			Total annualized costs [b]	Net benefits [c]		
			Low	Mean	High		Low	Mean	High
Evaluated at a 3% discount rate									
California	1	1	$0.02	$0.03	$0.06	$0.8	−$0.8	−$0.8	−$0.8
North Atlantic	5	4	0.03	0.07	0.14	4.6	−4.5	−4.5	−4.5
Mid-Atlantic	3	3	0.26	0.52	1.08	2.6	−2.3	−2.0	−1.5
Gulf of Mexico	7	7	0.33	0.64	1.33	9.1	−8.7	−8.4	−7.7
Great Lakes	23	19	0.18	0.34	0.64	10.1	−9.9	−9.7	−9.4
Inland	97	69	0.16	0.31	0.58	19.7	−19.5	−19.4	−19.1
National total	136	103	0.97	1.90	3.84	47.3	−46.4	−45.4	−43.5
Evaluated at a 7% discount rate									
California	1	1	0.01	0.02	0.05	1.0	−1.0	−0.9	−0.9
North Atlantic	5	4	0.02	0.05	0.11	5.0	−5.0	−5.0	−4.9
Mid-Atlantic	3	3	0.20	0.40	0.83	2.4	−2.2	−2.0	−1.6

[56] This section only includes benefits and costs for existing facilities because EPA was unable to assess benefits of reducing impingement mortality and entrainment at new offshore oil and gas facilities.

EXHIBIT X–1.—SUMMARY OF SOCIAL BENEFITS AND COSTS ''50 MGD FOR ALL WATERBODIES'' OPTION—Continued

[Millions; $ 2003]

Study region	Number of facilities subject to option	Number of facilities installing technology	Total annualized use value of I&E reductions [a]			Total annualized costs [b]	Net benefits [c]		
			Low	Mean	High		Low	Mean	High
Gulf of Mexico	7	7	0.26	0.51	1.06	10.2	−9.9	−9.7	−9.1
Great Lakes	23	19	0.14	0.26	0.50	10.2	−10.1	−9.9	−9.7
Inland	97	69	0.13	0.25	0.47	20.6	−20.5	−20.4	−20.2
National total	136	103	0.77	1.50	3.02	50.1	−49.3	−48.6	−47.1

[a] The total monetizable value of I&E reductions includes use benefits only. EPA evaluated non-use benefits only qualitatively. The ranges (low, medium, and high) for annualized use value is computed by adding the high end value for commercial fishing benefits (based on assumed producer surplus of 40% of gross revenue) to the low, mean, and high values for recreational fishing benefits respectively (see Section IX).

[b] Total costs are based on pre-tax facility costs. National total costs also include State, local, and Federal administrative costs of $0.6 million that cannot be attributed to individual study regions.

[c] Net benefits are computed by subtracting total annualized costs from total annual use values. The net benefits presented here are based on the comparison of a generally complete measure of social costs with an incomplete measure of social benefits, and should be interpreted with caution.

Exhibit X–2 presents a summary of total annualized benefits, total annualized costs, and net benefits for the ''200 MGD for All Waterbodies'' option. Under this option, 25 facilities (excluding baseline closures) are subject to the regulation. Of those facilities, it is assumed that 22 are required to install technologies to reduce impingement mortality and entrainment. The exhibit shows that the use benefits of the 200 MGD option are not projected to exceed the costs in any of the study regions. In the North Atlantic region, costs exceed use benefits by $0.5 million, evaluated at both the 3 percent and 7 percent discount rates. In the Inland region, costs are $12.1 million or $13.5 million greater than the use benefits. At the national level, EPA projects the costs of this option to exceed its use benefits by $21.5 million per year, discounted at 3 percent, or by $23.1 million per year, discounted at 7 percent.

EXHIBIT X–2.—SUMMARY OF SOCIAL BENEFITS AND COSTS ''200 MGD FOR ALL WATERBODIES'' OPTION

[Millions; $2003]

Study region	Number of facilities subject to option	Number of facilities installing technology	Total annualized use value of I&E reductions [a]			Total annualized costs [b]	Net benefits [c]		
			Low	Mean	High		Low	Mean	High
Evaluated at a 3% discount rate									
California	0	0	$0.00	$0.00	$0.00	$0.0	$0.0	$0.0	$0.0
North Atlantic	1	1	0.01	0.01	0.03	0.5	−0.5	−0.5	−0.5
Mid-Atlantic	2	2	0.23	0.46	0.96	2.0	−1.7	−1.5	−1.0
Gulf of Mexico	2	2	0.18	0.35	0.73	3.8	−3.6	−3.5	−3.1
Great Lakes	5	5	0.12	0.23	0.44	4.1	−3.9	−3.8	−3.6
Inland	14	12	0.11	0.21	0.39	12.3	−12.2	−12.1	−11.9
National total	25	22	0.65	1.26	2.54	22.8	−22.1	−21.5	−20.2
Evaluated at a 7% discount rate									
California	0	0	$0.00	$0.00	$0.00	$0.0	$0.0	$0.0	$0.0
North Atlantic	1	1	0.00	0.01	0.02	0.5	−0.5	−0.5	−0.4
Mid-Atlantic	2	2	0.17	0.35	0.73	1.8	−1.6	−1.4	−1.1
Gulf of Mexico	2	2	0.14	0.28	0.58	4.4	−4.2	−4.1	−3.8
Great Lakes	5	5	0.09	0.18	0.34	3.7	−3.6	−3.5	−3.3
Inland	14	12	0.09	0.17	0.32	13.7	−13.6	−13.5	−13.4
National total	25	22	0.51	0.98	1.98	24.1	−23.6	−23.1	−22.1

[a] The total monetizable value of I&E reductions includes use benefits only. EPA did not estimate non-use benefits quantitatively. The low and high use values reflect the range of recreational fishing values presented in Section 9 of the preamble. They were calculated using the Krinsky and Robb technique to estimate the 95th and 5th percentile limits on the marginal value per fish predicted by the meta-analysis.

[b] Total costs are based on pre-tax facility costs. National total costs also include State, local, and Federal administrative costs of $0.1 million that cannot be attributed to individual study regions.

[c] The net benefits presented here are based on the comparison of a generally complete measure of social costs with an incomplete measure of social benefits, and should be interpreted with caution.

Exhibit X–3 presents a summary of total annualized benefits, total annualized costs, and net benefits for the regulatory option with a design intake flow of 100 MGD or more for facilities withdrawing from oceans, estuaries, and tidal rivers, or the Great Lakes (''100 MGD for Certain Waterbodies''). Under this option, 19 facilities (excluding baseline closures) are subject to the regulation. Of those facilities, it is assumed that 18 are required to install technologies to reduce impingement mortality and entrainment, and one will incur permitting costs only. The exhibit shows that the use benefits of the 100 MGD for certain waterbodies option are not projected to exceed the costs in any of the study regions. In the Mid-Atlantic region, costs exceed use benefits by $1.5 million or $1.4 million, evaluated at 3 percent and 7 percent discount rates. In the Gulf of Mexico region, costs are $8.4 million or $9.7 million greater than the use benefits. At the national level, EPA projects the costs of this option to exceed its use benefits by $16.2 million per year, discounted at 3 percent, or by $17.2 million per year, discounted at 7 percent.

EXHIBIT X–3.—SUMMARY OF SOCIAL BENEFITS AND COSTS 100 MGD FOR CERTAIN WATERBODIES'' OPTION

[millions; $2003]

Study region	Number of facilities subject to option	Number of facilities installing technology	Total annualized use value of I&E reductions [a]			Total annualized Costs [b] [d]	Net benefits [c]		
			Low	Mean	High		Low	Mean	High
Evaluated at a 3% discount rate									
California	0	0	$0.00	$0.00	$0.00	$0.0	$0.0	$0.0	$0.0
North Atlantic	3	3	0.03	0.05	0.12	2.0	−2.0	−1.9	−1.9
Mid Atlantic	2	2	0.23	0.46	0.96	2.0	−1.7	−1.5	−1.0
Gulf of Mexico	7	7	0.33	0.64	1.33	9.1	−8.7	−8.4	−7.7
Great Lakes	8	6	0.14	0.26	0.49	4.5	−4.3	−4.2	−4.0
Inland	0	0	0.00	0.00	0.00	0.0	0.0	0.0	0.0
National total	19	18	0.72	1.41	2.90	17.6	−16.9	−16.2	−14.7
Evaluated at a 7% discount rate									
California	0	0	$0.00	$0.00	$0.00	$0.0	$0.0	$0.0	$0.0
North Atlantic	3	3	0.02	0.04	0.09	2.0	−2.0	−2.0	−1.9
Mid Atlantic	2	2	0.17	0.35	0.73	1.8	−1.6	−1.4	−1.1
Gulf of Mexico	7	7	0.26	0.51	1.06	10.2	−9.9	−9.7	−9.1
Great Lakes	8	6	0.11	0.20	0.38	4.1	−4.0	−3.9	−3.7
Inland	0	0	0.00	0.00	0.00	0.0	0.0	0.0	0.0
National total	19	18	0.56	1.10	2.26	18.3	−17.7	−17.2	−16.0

[a] The total monetizable value of I&E reductions includes use benefits only. EPA did not estimate non-use benefits quantitatively. The low and high use values reflect the range of recreational fishing values presented in Section 9 of the preamble. They were calculated using the Krinsky and Robb technique to estimate the 95th and 5th percentile limits on the marginal value per fish predicted by the meta-analysis.

[b] Total costs are based on pre-tax facility costs. National total costs also include State, local, and Federal administrative costs of $0.2 million that cannot be attributed to individual study regions.

[c] The net benefits presented here are based on the comparison of a generally complete measure of social costs with an incomplete measure of social benefits, and should be interpreted with caution.

B. Break-even Analysis

Estimating non-use values is an extremely challenging and uncertain exercise, particularly when, due to time and resource constraints, primary research using stated preference methods was not a feasible option for this proposed rule. In Section IX.D.5 above, EPA described possible alternative approaches for developing non-use benefit estimates based on benefits transfer and associated methods. Due to the uncertainties of providing estimates of the magnitude of non-use values associated with the regulatory options considered for this proposal, this section provides an alternative approach for evaluating the significance of non-use values. The approach used here applies a ''break-even'' analysis to identify what non-use values would have to be in order for the options to have monetized benefits that are equal to costs.

The break-even approach uses EPA's estimated commercial and recreational use benefits for the regulatory options and subtracts them from the estimated annual compliance costs incurred by existing facilities subject to the regulatory options. The resulting ''net cost'' enables one to work backwards to estimate what non-use values would need to be in order for total annual benefits to equal annualized costs. EPA computed the per household willingness-to-pay for all three options proposed today and found that the non-use values necessary to equate total annual benefits with total annual social cost ranged from $1.43 per household, for the ''100 MGD for Certain Waterbodies'' option discounted at 3 percent, to $2.13 per household for the ''50 MDG for All Water bodies'' option discounted at 7 percent. EPA also calculated the break-even non-use value per (age-1 equivalent) fish saved. The per fish value necessary to have the total annual costs and benefits of the proposed options equate range from $0.54 for the ''100 MGD for Certain Waterbodies'' option, discounted at 3 percent, to $0.98 for the ''50 MDG for All Water bodies'' option, discounted at 7 percent. For a detailed discussion of the estimation and results of both the per household and per fish break-even values see the Regional Analysis Document.

XI. Statutory and Executive Order Reviews

A. E.O. 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this proposed rule is a ''significant regulatory action.'' As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 2169.01.

The information collected under today's proposed rule would assist EPA in regulating environmental impacts, namely impingement mortality and entrainment, at cooling water intake structures at Phase III facilities and new offshore oil and gas extraction facilities. This information would be used by these parties to prepare comprehensive demonstration studies, monitor impingement mortality and entrainment, verify compliance, and prepare annual/biennial reports as required under today's proposal. The information collected would be reviewed by EPA and State Directors to ensure that appropriate National Pollutant Discharge Elimination System (NPDES) permit conditions regulating cooling water intake structures would be developed. Compliance with the applicable information collection requirements imposed under this proposed rule is mandatory (*see* §§ 122.21(r), 125.136, 125.137, 125.138, 125.104, 125.105, 125.106, 125.107, 125.108).

EPA does not consider the specific data that would be collected under this proposed rule to be confidential business information. However, if a respondent does consider this information to be confidential, the respondent may request that such information be treated as confidential. All confidential data will be handled in accordance with 40 CFR 122.7, 40 CFR Part 2, and EPA's Security Manual Part III, Chapter 9, dated August 9, 1976.

Today's proposed rule would modify regulations at § 122.21 to require existing Phase III facilities and new offshore oil and gas extraction facilities to prepare and submit some of the same information required for Phase I and Phase II facilities. The proposed application requirements would require owners or operators of Phase III existing facilities to submit two general categories of information when they apply for a reissued NPDES permit. The general categories of information would include (1) permit application information, and (2) verification monitoring data. A detailed list of required data items is provided below.

As discussed in section II of the preamble, EPA is proposing three regulatory options for existing facilities in today's proposed rule based on design intake flow including: (1) A 50 MGD option for facilities withdrawing water from all waterbody types; (2) a 200 MGD option for facilities withdrawing water from all waterbody types; and (3) a 100 MGD option for facilities which withdraw water specifically from an ocean, estuary, tidal river, or one of the Great Lakes. Under the co-proposed 50 MGD threshold-based option, the total average annual burden, during the first three years after promulgation of the rule, of the information collection requirements associated with today's proposed rule is estimated at 215,885 hours. The corresponding estimates of average annual cost other than labor (labor and non-labor costs are included in the total cost of the proposed rule discussed in section VIII of this preamble) is $2.81 million for 87 facilities (56 existing manufacturers and 31 new offshore oil and gas facilities) and 45 States and one Territory during the first three years after promulgation of the rule. Under the co-proposed 200 MGD threshold-based option, the total average annual burden, during the first three years after promulgation of the rule, of the information collection requirements is estimated at 62,280 hours. The corresponding average annual non-labor cost is $1.46 million for 44 facilities (13 existing manufacturers and 31 new offshore oil and gas facilities), and 45 States and one Territory during the first three years after promulgation of the rule. Under the co-proposed 100 MGD threshold-based option, the total average annual burden, during the first three years after promulgation of the rule, of the information collection requirements is estimated at 85,622 hours. The corresponding average annual non-labor cost is $1.62 million for 42 facilities (11 existing manufacturers and 31 new offshore oil and gas facilities), and 45 States and one Territory during the first three years after promulgation of the rule.

Non-labor costs include activities such as capital costs for remote monitoring devices, laboratory services, photocopying, and the purchase of supplies. The burden and costs are for the information collection, reporting, and recordkeeping requirements for the three-year period beginning with the assumed effective date of today's rule. Additional information collection requirements will occur after this initial three-year period as existing facilities continue to be issued permit renewals, new offshore oil and gas extraction facilities are issued permits, and such requirements will be counted in a subsequent information collection request.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Studies to be submitted by both Phase III existing facilities and new offshore oil and gas extraction facilities under today's proposed rule are listed below. Both Phase III existing facilities and

new offshore oil and gas fixed platforms would be required to collect the general information listed below.

- Source Water Physical Data (§ 122.21(r)(2)) (both Phase III existing facilities and new offshore oil and gas facilities)
- Cooling Water Intake Structure Data (§ 122.21(r)(3)) ((both Phase III existing facilities and new offshore oil and gas facilities)
- Cooling Water System Description (§ 122.21(r)(5)) (Phase III existing facilities only)

Depending on the compliance alternative selected by the individual facility, Phase III existing facilities may be required to submit the following information:

- Proposal for Information Collection (§ 125.104(b)(1))
- Source Waterbody Flow Information (§ 125.104(b)(2))
- Impingement Mortality and/or Entrainment Characterization Study (§ 125.104(b)(3))
- Technology Compliance and Assessment Information (§ 125.104(b)(4))
- Restoration Plan (§ 125.104(b)(5))
- Information to Support Site-specific Determination of Best Technology Available for Minimizing Adverse Environmental Impact (§ 125.104(b)(6))
- Verification Monitoring Plan (§ 125.104(b)(7))

New offshore oil and gas extraction facilities would be required to submit the following information under Track I:

- Source Water Baseline Biological Characterization Data (§ 122.21(r)(4)) (not required for non-fixed facilities)
- Velocity Information (§ 125.136(b)(2))
- Source Waterbody Flow Information (§ 125.136(b)(3)) (not required for non-fixed facilities)
- Design and Construction Technology Plan (§ 125.136(b)(4))

In addition to the information requirements of the permit renewal application, NPDES permits normally specify monitoring and reporting requirements to be met by the permitted entity. Existing facilities that fall within the scope of this proposed rule would be required to perform biological monitoring as required by the Director to demonstrate compliance. New offshore oil and gas extraction fixed facilities would be required to perform monitoring as determined by the Track I or Track II requirements in § 125.136. Additional ambient water quality monitoring may also be required of facilities depending on the specifications of their permits. New offshore oil and gas extraction facilities would be expected to analyze the results from their monitoring efforts and provide these results in an annual status report to the permitting authority. Existing Phase III facilities would be required to submit a status report every two years that included appropriate monitoring data and any other information specified by the Director. Finally, facilities would be required to maintain records of all submitted documents, supporting materials, and monitoring results for at least three years. (Note that the Director may require that records be kept for a longer period to coincide with the life of the NPDES permit.)

All impacted facilities would carry out the specific activities necessary to fulfill the general information collection requirements. The estimated burden includes developing a water balance diagram that can be used to identify the proportion of intake water used for cooling, make-up, and process water. Facilities would also gather data to calculate the reduction in impingement mortality and entrainment of all life stages of fish and shellfish that would be achieved by the technologies and operational measures they select. The burden estimates include sampling, assessing the source waterbody, estimating the magnitude of impingement mortality and entrainment, and reporting results in a comprehensive demonstration study. The burden may also include conducting a pilot study to evaluate the suitability of the technologies and operational measures based on the species that are found at the site.

Some of the Phase III existing facilities (those choosing to use restoration measures to maintain fish and shellfish) would need to prepare a plan documenting the restoration measures they would implement and how they would demonstrate that the restoration measures were effective. However, for purposes of this paperwork burden analysis, EPA assumed all facilities would comply using design and construction technologies.

Some facilities may choose to request a site-specific determination of best technology available because of costs significantly greater than those EPA considered in establishing the performance standards or because costs are significantly greater than the benefits of complying with the performance standards. These facilities would be required to perform a comprehensive cost evaluation study and, if applicable, a valuation of the monetized benefits of reducing impingement mortality and entrainment, as well as submitting a site-specific technology plan characterizing the design and construction technologies, operational measures and restoration measures they have selected. However, for purposes of this paperwork burden estimate, EPA assumed all facilities would comply by meeting the applicable performance standards.

The assumption that facilities will not use restoration or request a site-specific determination of best technology available may lead to an underestimate of paperwork burden, since there are additional documentation requirements associated with both of these approaches. However, since both are optional, EPA assumes that facilities would not choose them unless total burden, including both paperwork burden and compliance costs is less than the total burden under the approach EPA assumed for its PRA analysis.

Exhibits XI–1 through 3 present a summary of the average burden estimates for a facility to prepare a permit application and monitor and report on cooling water intake structure operations for the three options for existing manufacturers as required by this proposed rule. Exhibit XI–4 presents a summary of the average burden estimates for a facility to prepare a permit application and monitor and report on cooling water intake structure operations for new offshore oil and gas extraction facilities as required by this proposed rule. For the purpose of estimating the average burden for new offshore oil and gas extraction facilities, EPA assumed all facilities would pursue Track I of today's proposed rule. It is unknown how many facilities would select Track I versus Track II so the actual burden estimate may be slightly higher or lower than that presented in this section.

EXHIBIT XI–1.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES

[50 MGD all waterbodies option]

Activities	Annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost [b]
Start-up Activities	43	2,121	0	50	56	19	803	40,527
Permit Application Activities	247	9,951	0	510	56	19	4,611	195,279
Proposal for Collection of Information for Comprehensive Demonstration Study	272	12,344	0	770	43	14	3,899	187,964
FW River/Stream Source Water Body Flow Information	100	3,381	0	200	15	5	500	17,904
FW Lake/Reservoir Source Water Body Flow Information	112	3,946	0	200	2	1	75	2,764
Design and Construction Technology Plan (Impingement)	31	1,368	0	0	31	10	320	14,132
Design and Construction Technology Plan (Entrainment)	31	1,368	0	0	20	7	207	9,117
Design and Construction Technology Plan (All)	30	922	0	380	33	11	330	14,322
Freshwater Baseline Monitoring for Impingement Mortality and/or Entrainment Study	2,210	102,549	0	1,538	23	13	29,460	1,387,834
Freshwater Monitoring for Impingement Mortality Study	1,105	51,544	0	773	23	13	14,727	697,560
Freshwater Monitoring for Entrainment Study	845	39,727	0	39,596	4	3	2,252	211,527
Marine Baseline Monitoring for Impingement Mortality and/or Entrainment Study	2,841	131,350	0	1,970	20	19	53,041	2,488,651
Marine Monitoring for Impingement Mortality Study	1,414	65,430	0	981	16	15	21,680	1,018,309
Marine Monitoring for Entrainment Study	1,076	50,083	0	51,451	20	19	20,090	1,895,311
Impingement Mortality & Entrainment Characterization Study Initial Analysis	373	22,042	0	0	43	14	5,346	315,931
Impingement Mortality & Entrainment Characterization Study Final Report	399	18,875	0	614	33	11	4,389	214,381
Pilot Study Impingement Monitoring (Freshwater) for Pilot Study	661	33,927	804,252	0	1	0	220	279,393
Pilot Study Entrainment Monitoring (Freshwater) for Pilot Study	541	28,473	0	6,000	1	0	180	11,491
Pilot Study Impingement Monitoring (Marine) for Pilot Study	831	41,572	189,062	0	10	3	2,768	768,781
Pilot Study Entrainment Monitoring (Marine) for Pilot Study	675	34,482	0	7,800	10	3	2,248	140,941
Pilot Study Entrainment Monitoring (All) for Pilot Study	354	17,487	0	1,020	11	4	1,298	67,858
Technology Installation and Operation Plan	52	2,372	0	80	35	12	607	28,611

EXHIBIT XI–1.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES—Continued

[50 MGD all waterbodies option]

Activities	Annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost [b]
Verification Monitoring Plan	128	5,918	0	410	35	12	1,493	73,827
Total for NPDES Permit Application Activities	.....	.....	.....	.....	56	227	170,544	10,082,416
Average Burden and Costs per Facility for Annual Monitoring and Reporting Activities								
Annual Monitoring for Impingement (Freshwater)	379	18,504	0	510	11	5	2,021	101,406
Annual Monitoring for Impingement (Marine)	482	23,564	0	660	12	5	2,569	129,193
Annual Monitoring for Entrainment (Freshwater)	614	30,376	0	8,310	4	2	1,228	77,371
Annual Monitoring for Entrainment (Marine)	776	38,069	0	10,800	14	7	5,173	325,790
Biannual Status Report Activities	324	16,618	0	770	27	9	2,916	156,492
Verification Study	118	6,772	0	510	27	9	1,062	65,540
Total for Annual Activities	.....	.....	.....	.....	27	37	14,969	855,792

[a] Cost of supplies, filing cabinets, photocopying, boat renting, etc.

[b] Costs for restoration activities and site-specific studies were not estimated as EPA cannot determine how many facilities would choose to select this option and the option is voluntary.

EXHIBIT XI–2.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES

[200 MGD all waterbodies option]

Activity	Annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost
Start-up Activities	43	$2,121	$0	$50	13	4	186	$9,408
Permit Application Activities	247	9,951	0	510	13	4	1,070	45,333
Proposal for Collection of Information for Comprehensive Demonstration Study	272	12,344	0	770	9	3	816	39,341
FW River/Stream Source Water Body Flow Information	100	3,381	0	200	1	0	33	1,194
FW Lake/Reservoir Source Water Body Flow Information	.....	0	0	200	.....	0	0	0
Design and Construction Technology Plan (Impingement)	31	1,368	0	0	5	2	52	2,279
Design and Construction Technology Plan (Entrainment)	31	1,368	0	0	4	1	41	1,823
Design and Construction Technology Plan (All)	30	922	0	380	5	2	50	2,170
Freshwater Baseline Monitoring for Impingement Mortality and/or Entrainment Study	2,210	102,549	0	1,538	2	1	2,210	104,088
Freshwater Monitoring for Impingement Mortality Study	1,105	51,544	0	773	2	1	1,105	52,317
Freshwater Monitoring for Entrainment Study	.....	0	0	39,596	.....	0	0	0

EXHIBIT XI–2.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES—Continued

[200 MGD all waterbodies option]

Activity	Annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility[a]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost
Marine Baseline Monitoring for Impingement Mortality and/or Entrainment Study	2,841	131,350	0	1,970	7	6	17,049	799,923
Marine Monitoring for Impingement Mortality Study	1,414	65,430	0	981	6	5	7,541	354,194
Marine Monitoring for Entrainment Study	1,076	50,083	0	51,451	7	6	6,458	609,207
Impingement Mortality & Entrainment Characterization Study Initial Analysis	373	22,042	0	0	9	3	1,119	66,125
Impingement Mortality & Entrainment Characterization Study Final Report	399	18,875	0	614	5	2	665	32,482
Pilot Study Impingement Monitoring (Freshwater) for Pilot Study	661	33,927	804,252	0	1	0	220	279,393
Pilot Study Entrainment Monitoring (Freshwater) for Pilot Study	541	28,473	0	6,000	1	0	180	11,491
Pilot Study Impingement Monitoring (Marine) for Pilot Study	831	41,572	183,241	0	4	1	1,107	299,751
Pilot Study Entrainment Monitoring (Marine) for Pilot Study	675	34,482	0	7,800	4	1	899	56,376
Pilot Study Entrainment Monitoring (All) for Pilot Study	354	17,487	0	1,020	5	2	590	30,845
Technology Installation and Operation Plan	52	2,372	0	80	6	2	104	4,905
Verification Monitoring Plan	128	5,918	0	410	6	2	256	12,656
Total for NPDES Permit Application Activities	.....	.....	.....	.....	13	50	41,752	2,815,302
Average Burden and Costs per Facility for Annual Monitoring and Reporting Activities								
Annual Monitoring for Impingement (Freshwater)	379	18,504	0	510	1	1	253	12,676
Annual Monitoring for Impingement (Marine)	482	23,564	0	660	3	1	482	24,224
Annual Monitoring for Entrainment (Freshwater)	614	30,376	0	8,310	1	0	205	12,895
Annual Monitoring for Entrainment (Marine)	776	38,069	0	10,800	3	1	776	48,869
Biannual Status Report Activities	324	16,618	0	770	5	2	540	28,980
Verification Study	118	6,772	0	510	5	2	197	12,137
Total for Annual Activities	.....	.....	.....	.....	5	7	2,452	139,780

[a] Cost of supplies, filing cabinets, photocopying, boat renting, etc.

EXHIBIT XI–3.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES

[100 MGD certain waterbodies option]

Activity	Annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Aveage annual hours	Average annual cost
Start-up Activities	43	$2,121	$0	$50	11	4	158	$7,961
Permit Application Activities	247	9,951	0	510	11	4	906	38,358
Proposal for Collection of Information for Comprehensive Demonstration Study	272	12,344	0	770	11	4	997	48,084
FW River/Stream Source Water Body Flow Information	—	0	0	0	—	0	0	0
FW Lake/Reservoir Source Water Body Flow Information	—	0	0	0	—	0	0	0
Design and Construction Technology Plan (Impingement)	31	1,368	0	0	8	3	83	3,647
Design and Construction Technology Plan (Entrainment)	31	1,368	0	0	8	3	83	3,647
Design and Construction Technology Plan (All)	30	922	0	380	8	3	80	3,472
Freshwater Baseline Monitoring for Impingement Mortality and/or Entrainment Study	—	0	0	1,538	—	0	0	0
Freshwater Monitoring for Impingement Mortality Study	—	0	0	773	—	0	0	0
Freshwater Monitoring for Entrainment Study	—	0	0	039,596	—	0	0	0
Marine Baseline Monitoring for Impingement Mortality and/or Entrainment Study	2,841	131,350	0	1,970	11	10	28,415	1,333,206
Marine Monitoring for Impingement Mortality Study	1,414	65,430	0	981	10	9	13,1976	19,840
Marine Monitoring for Entrainment Study	1,076	50,083	0	051,451	11	10	10,763	1,015,345
Impingement Mortality & Entrainment Characterization Study Initial Analysis	373	22,042	0	0	11	4	1,368	80,820
Impingement Mortality & Entrainment Characterization Study Final Report	399	18,875	0	614	8	3	1,064	51,971
Pilot Study Impingement Monitoring (Freshwater) for Pilot Study	—	0	0	0	—	0	0	0
Pilot Study Entrainment Monitoring (Freshwater) for Pilot Study	—	0	0	6,000	—	0	0	0
Pilot Study Impingement Monitoring (Marine) for Pilot Study	831	41,572	221,548	0	6	2	1,661	526,240
Pilot Study Entrainment Monitoring (Marine) for Pilot Study	675	34,482	0	7,800	6	2	1,349	84,564
Pilot Study Entrainment Monitoring (All) for Pilot Study	354	17,487	0	1,020	6	2	708	37,014
Technology Installation and Operation Plan	52	2,372	0	80	8	3	139	6,540

EXHIBIT XI–3.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES—Continued

[100 MGD certain waterbodies option]

Activity	Annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Aveage annual hours	Average annual cost
Verification Monitoring Plan	128	5,918	0	410	8	3	341	16,875
Total for NPDES Permit Application Activities					11	66	61,310	3,877,583
Average Burden and Costs per Facility for Annual Monitoring and Reporting Activities								
Annual Monitoring for Impingement (Freshwater)	—	0	0	510	—	0	0	0
Annual Monitoring for Impingement (Marine)	482	23,564	0	660	7	3	1,284	64,596
Annual Monitoring for Entrainment (Freshwater)	—	0	0	8,310	—	0	0	0
Annual Monitoring for Entrainment (Marine)	776	38,069	0	10,800	7	3	2,069	130,316
Biannual Status Report Activities	324	16,618	0	770	7	2	756	40,572
Verification Study	118	6,772	0	510	7	2	275	16,992
Total for Annual Activities					7	10	4,385	252,476

[a] Cost of supplies, filing cabinets, photocopying, boat renting, etc.

EXHIBIT XI–4.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES

[New offshore oil and gas extraction facilities [a]]

Activity	Annual hours per facility	Annual labor cost per facility	Annuallized capital cost per facility	Annual O&M cost per facility [a b]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost
Start-up Activities	43	$2,121	$0	$50	31	10	444	$22,435
Permit Application Activities	25	795	0	130	19	6	158	5,857
Source Water Body Flow Information	38	1,341	0	75	19	6	241	8,968
CWIS Velocity Information	—	0	0	0	—	0	0	0
Design and Construction Technology Plan (Impingement Only)	35	1,021	0	120	15	5	175	5,706
Design and Construction Technology Plan (Entrainment Only)	35	1,021	0	120	1	0	12	380
Design and Construction Technology Plan (Impingement & Entrainment)	38	1,162	0	120	3	1	38	1,282
Develop Regional Study Design and Submit to Director	78	5,007	0	0	2	1	52	3,338
Deep Water Baseline Monitoring for Source Water Baseline Biological Characterization Study	309	17,260	0	43,200	9	9	2,778	544,137
Deep Water Impingement Monitoring for Source Water Baseline Biological Characterization Study	144	7,987	7,621	667	9	9	1,296	146,473

EXHIBIT XI–4.—AVERAGE ANNUAL REPORTING BURDEN AND COSTS PER FACILITY FOR NPDES PERMIT APPLICATION AND MONITORING AND REPORTING ACTIVITIES—Continued

[New offshore oil and gas extraction facilities [a]]

Activity	Annual hours per facility	Annual labor cost per facility	Annuallized capital cost per facility	Annual O&M cost per facility [a b]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost
Deep Water Entrainment Monitoring for Source Water Baseline Biological Characterization Study	144	7,987	0	3,120	3	3	432	33,321
Alaska Basline Monitoring for Source Water Baseline Biological Characterization Study	384	20,337	0	49,200	1	1	384	69,537
Alaska Entrainment Monitoring for Source Water Baseline Biological Characterization Study	192	10,169	0	3,120	1	1	192	13,289
Initial Sourcewater Baseline Biological Characterization Data	366	20,584	0	0	10	3	1,220	68,613
Sourcewater Baseline Biological Characterization Data Study Final Regional Report	288	18,389	0	0	2	1	192	12,259
Use Regional Study Results for Individual Facility Studies	166	7,591	0	0	19	6	1,051	48,079
Source Water Baseline Biological Characterization Study Other Direct Costs for Deep Water	—	0	0	13,270	9	3	0	39,810
Source Water Baseline Biological Characterization Study Other Direct Costs for Alaska	—	0	0	19,910	1	0	0	6,637
Total for NPDES Permit Application Activities	.....	.....	.....	.....	31	67	8,665	1,030,123
Average Burden and Costs per Facility for Annual Monitoring and Reporting Activities								
Biological Monitoring for Impingement	530	25,823	0	1,660	—	0	0	0
Biological Monitoring for Entrainment	370	17,647	0	15,780	—	0	0	0
Biological Monitoring for Entrainment (Alaska)	516	24,298	0	21,780	—	0	0	0
Velocity Monitoring	163	5,692	0	500	13	7	1,087	41,283
Yearly Status Report Activities	223	11,304	0	770	13	7	1,487	80,495
Total for Annual Activities	.....	.....	.....	.....	13	14	2,573	121,778

[a] Track I requirements only estimated.
[b] Cost of supplies, filing cabinets, photocopying, boat renting, etc.

EPA believes that all 45 States and one Territory with NPDES permitting authority would undergo start-up activities in preparation for administering the provisions of the proposed rule. As part of these start-up activities, States and Territories would be expected to train junior technical staff to review materials submitted by facilities, and then use these materials to evaluate compliance with the specific conditions of each facility's NPDES permit.

Each State's/Territory's actual burden associated with reviewing submitted materials, writing permits, and tracking compliance would depend on the number of in-scope facilities that would come up for permit renewal in the State/Territory during the ICR approval period and which flow threshold-based option EPA selects for Phase III existing facilities. EPA expects that State and Territory technical and clerical staff will spend time gathering, preparing, and submitting the various documents. EPA's burden estimates reflect the general staffing and level of expertise that is typical in States/Territories that administer the NPDES permitting program. EPA considered the time and qualifications necessary to complete various tasks such as reviewing

submitted documents and supporting materials, verifying data sources, planning responses, determining specific permit requirements, writing the actual permit, and conferring with facilities and the interested public. Exhibits XI–5 through 7 provide a summary of the average burden estimates for States/Territories performing various activities for existing manufacturing facilities required by the proposed rule. States/Territories are not involved in administering the permits for new offshore oil and gas extraction facilities since the offshore oil and gas industry is currently permitted under general permits at the regional EPA level. This practice is likely to continue in the forseeable future.

EXHIBIT XI–5.—ESTIMATING STATE/TERRITORY AVERAGE BURDEN AND COSTS FOR ACTIVITIES

[50 MGD all waterbodies option]

Activity	Average annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost
Director Start-up Activities	100	$3,894	$0	$50	46	15	1,533	$60,475
Director Permit Issuance Activities	803	35,979	0	310	56	19	14,989	677,398
Verification Study Review	—	0	0	10	—	0	0	0
Annual Director Activities	50	1,851	0	30	27	9	450	16,932
Total for Director Activities					46	43	16,972	754,804

[a] Cost of supplies, filing cabinets, photocopying, boat renting, etc.

EXHIBIT XI–6.—ESTIMATING STATE/TERRITORY AVERAGE BURDEN AND COSTS FOR ACTIVITIES

[200 MGD all waterbodies option]

Activity	Average annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost
Director Start-up Activities	100	$3,894	$0	$50	46	15	1,533	$60,475
Director Permit Issuance Activities	706	31,417	0	310	13		43,060	137,482
Verification Study Review	—	0	0	10	—	0	0	0
Annual Director Activities	50	1,851	0	30	5	2	83	3,136
Total for Director Activities					46	21	4,677	201,092

[a] Cost of supplies, filing cabinets, photocopying, boat renting, etc.

EXHIBIT XI–7.—ESTIMATING STATE/TERRITORY AVERAGE BURDEN AND COSTS FOR ACTIVITIES

[100 MGD All Waterbodies Option]

Activity	Average annual hours per facility	Annual labor cost per facility	Annual capital cost per facility	Annual O&M cost per facility [a]	Three year respondent total	Average annual frequency of responses	Average annual hours	Average annual cost
Director Start-up Activities	100	$3,894	$0	$50	46	15	1,533	$60,475
Director Permit Issuance Activities	1330	60,163	0	310	11	4	4,878	221,733
Verification Study Review	—	0	0	10	—	0	0	0
Annual Director Activities	50	1,851	0	30	7	2	117	4,390
Total for Director Activities					46	21	6,528	286,598

[a] Cost of supplies, filing cabinets, photocopying, boat renting, etc.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR Part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number OW–2003–0005. Submit any comments related to the ICR for this proposed rule to EPA and OMB. See ''Addresses'' section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs,

Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after November 24, 2004, a comment to OMB is best assured of having its full effect if OMB receives it by December 27, 2004. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This section summarizes EPA's analyses in compliance with the RFA.

1. Definition of Small Entity

Small entities include small businesses, small organizations, and small governmental jurisdictions. For assessing the impacts of today's proposal on small entities, a small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

The SBA small business size standards changed from a SIC code-based system to a NAICS code-based system on October 1, 2000. Since EPA conducted its data collection effort for existing facilities before this change, EPA performed the small entity analysis for existing facilities based on SIC codes. EPA then conducted a subsequent analysis to determine if the size standards based on NAICS codes would have any effect on the results of the small entity analysis. This analysis showed that for the three co-proposed options, there would be no changes to the small entity determination, and therefore to small entity impacts, as a result of switching from SIC-based size standards to NAICS-based size standards.

2. Certification Statement

After considering the economic impacts of today's proposal on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposal applies to existing facilities that employ a cooling water intake structure and are designed to withdraw either (1) 50 MGD or more from all waterbodies, (2) 100 MGD or more from certain waterbodies, or (3) 200 MGD or more from all waterbodies that are waters of the United States. It also applies to new offshore oil and gas extraction facilities that withdraw greater than 2 MGD from waters of the United States.

3. Statement of Basis

EPA estimates that this proposal will not apply national categorical standards to any small entities in the Manufacturers or Electric Generators industry segments (entities that operate facilities subject to permitting based on best professional judgement are excluded from this analysis). In the new offshore oil and gas extraction industry segment, EPA estimates that the proposed option will apply national standards to only one small entity, a new offshore oil and gas platform. EPA estimates that this entity would incur annualized, after-tax compliance costs of less than 0.1 percent of annual revenue. EPA does not know precisely which firms would be undertaking construction of new offshore oil and gas extraction facilities. However, based on the firms that are currently active in building the types of facilities representative of those covered by the rulemaking, EPA believes that the small firm analyzed represents the smallest firm that would be involved in such activities over the period of the analysis.

4. Summary of Small Business Advocacy Review Panel

Although the RFA does not require a Small Business Advocacy Review (SBAR) Panel for this rule (because EPA has determined that this proposal would not have a significant economic impact on a substantial number of small entities), EPA convened a panel to obtain advice and recommendations from small entity representatives (SERs) potentially subject to this proposed rule's requirements because at the time EPA had not yet determined the scope of the proposed rule and thus the potential for small entity impacts. This section summarizes EPA's small entity outreach and information on the composition, process, and findings of the SBAR panel.

a. Summary of Small Entity Outreach

EPA actively involved stakeholders, including small entities, in the development of the proposed rule in order to ensure the quality of information, identify and understand potential implementation and compliance issues, and explore regulatory alternatives. EPA conducted numerous meetings with the electric power industry over the past six years and met twice with manufacturing industry representatives in the past two years; during these meetings, EPA received direct input about the impacts of the proposed rule on the industry.

In the past three years, EPA held two conference calls with small entity representatives from the manufacturing and electric power industries to improve the Agency's understanding of cooling water intakes in these industries, and of the potential impacts of new requirements from an economic and business perspective. Before convening the Panel, EPA held a conference call/meeting on October 1, 2002, and another on January 22, 2004, to receive information from prospective SERs about plans for convening the Panel and their early concerns about the planned proposed regulation.

b. Panel Members

The Panel consisted of EPA's Small Business Advocacy Chairperson, the Director of the Engineering and Analysis Division of the Office of Science and Technology (EPA/OW), the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Chief Counsel for Advocacy of the Small Business Administration (SBA).

c. SERs

After consultation with the Small Business Administration Office of Advocacy, EPA invited six municipal power plant representatives and six representatives from manufacturing industries to serve as potential SERs during the pre-panel outreach process. Ultimately, three municipal power plant representatives and four representatives from manufacturing industries provided comments to the Panel.

d. Summary of Panel Process

The Panel convened on February 27, 2004. The Panel held an outreach meeting and telephone conference for SERs on March 16, 2004. Materials were provided to SERs in advance of the meeting and additional materials on specific topics of interest to SERs were provided during the Panel process. SERs provided comments to the Panel on (1)

the number and types of small entities affected; (2) potential reporting, record keeping, and compliance requirements; (3) related Federal rules; (4) regulatory flexibility alternatives; and (5) methodological issues.

The Panel evaluated the assembled materials and small entity comments on issues related to the elements of the initial regulatory flexibility analysis (IRFA). A copy of the Panel report, ''Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule for Cooling Water Intake Structures at Section 316(b) Phase III Facilities,'' is included in the docket for this proposed rule (DCN 7–0006).

e. Panel Recommendations

The Panel provided several recommendations pertaining to reporting, record keeping, and compliance requirements; regulatory flexibility alternatives; and methodological issues relevant to the assessment of the impacts of a Phase III rule on small entities. The following is a summary of the Panel's recommendations and EPA's responses:

- *Recommendation:* The Panel noted that significant implementation flexibility was included in the Phase II rule. For example, facilities were allowed up to three and one half years following rule promulgation to submit their initial demonstration study and related application materials. The Panel recommended that this level of flexibility be provided for Phase III requirements. The Panel also recommended that EPA consider the availability of contractor resources as it develops the implementation schedule for Phase III.

Response: EPA has provided in the proposed rule the same implementation flexibility contained in the Phase II rule. EPA will consider the availability of contractor resources and would like to receive comments on this issue.

- *Recommendation:* The Panel recommended that EPA analyze a range of potential applicability thresholds, particularly those between 20 MGD and 50 MGD. The Panel believed that an effective way to substantially reduce potential economic impacts on small entities would be to set an applicability threshold of 20 MGD. Facilities below 20 MGD represent a small proportion of the total flow associated with the Phase III rulemaking.

Response: In response to the Panel's recommendations, EPA analyzed several policy options with different regulatory requirements and applicability thresholds based on flow range categories. As a result of these analyses, EPA is co-proposing three options with minimum applicability thresholds of 50 MGD, 100 MGD, and 200 MGD, respectively. Under these thresholds, no Phase III existing facilities owned by small entities would be subject to national categorical requirements.

- *Recommendation:* The Panel recognized the implementation challenges associated with using actual flows instead of design flows to structure regulatory requirements. However, the Panel believed that this approach merits further consideration.

Response: EPA notes that since the proposed thresholds exclude existing small entities, no implementation challenges to small entities would result. With regard to facilities within the scope of the proposed rule, EPA believes that it would be most appropriate to be consistent with the regulatory approach taken in Phase II.

- *Recommendation:* The American Public Power Association (APPA) raised several methodological issues regarding EPA's analysis of the impacts of a Phase III rule on small entities, including alternate estimates of the number of regulated small electric utilities and issues concerning the downtime required for retrofitting. The Panel recommended that EPA seek further information from APPA to identify any necessary modifications to the assumptions used for its cost and economic impact analyses. The Panel also recommended that EPA review its assumptions used to develop costs and economic impacts to ensure that these assumptions are appropriate for facilities with smaller budgets and staffs.

Response: Because of the choice EPA made to propose larger design intake flow thresholds (*i.e.*, 50 MGD, 100 MGD, and 200 MGD), all electric power producers not covered by Phase II will be exempt from the national categorical requirements of this proposed rule, but will continue to be subject to site-specific 316(b) requirements based on the best professional judgment of the permit writer.

5. Small Entity Flexibility Analysis

Despite the determination that this rule would not have a significant economic impact on a substantial number of small entities, EPA prepared a Small Entity Flexibility Analysis that has all the components of an Initial Regulatory Flexibility Analysis (IRFA). An IRFA examines the impact of a proposed rule on small entities along with regulatory alternatives that could reduce that impact. The Small Entity Flexibility Analysis (which is described in detail in the Economic Analysis document) is available for review in the docket.

Under the three co-proposed options, EPA estimates that only one small entity (a new offshore oil and gas extraction facility) would be subject to the national categorical requirements. Under these thresholds, no Phase III existing facilities owned by small entities would be subject to national categorical requirements. This facility is estimated to have a cost-to-revenue ratio of less than 0.1 percent.

EPA continues to be interested in the potential impacts of this proposal on small entities and welcomes comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant intergovernmental mandates, and informing, educating, and advising small governments on compliance with regulatory requirements.

The following subsections present a brief summary of UMRA considerations for the proposed rule. Each subsection includes the results of the proposed option for new offshore oil and gas extraction facilities together with one of the three co-proposed options for existing facilities.[57]

- *2 MGD Option for new facilities and 50 MGD All Waterbodies Option for existing facilities:* EPA estimates the total annualized after-tax costs of compliance to be $44.8 million (2003$). All of these direct facility costs are incurred by the private sector (including 136 manufacturing facilities and 124 offshore oil and gas extraction facilities). No facility owned by State or local governments is subject to the national requirements under this proposed option. Additionally, State and local permitting authorities are estimated to incur $0.5 million annually to administer this option, including labor costs to write permits and to conduct compliance monitoring and enforcement activities. As required per section 202 of the UMRA, EPA estimates that the highest undiscounted after-tax cost incurred by the private sector in any one year is approximately $280 million in 2011.
- *2 MGD Option for new facilities and 200 MGD All Waterbodies Option for existing facilities:* EPA estimates the total annualized after-tax costs of compliance to be $21.4 million (2003$). All of these direct facility costs are incurred by the private sector (including 25 manufacturing facilities and 124 offshore oil and gas extraction facilities). No facility owned by State or local governments is subject to the national requirements under this proposed option. Additionally, State and local permitting authorities are estimated to incur $0.1 million annually to administer this option, including labor costs to write permits and to conduct compliance monitoring and enforcement activities. As required per section 202 of the UMRA, EPA estimates that the highest undiscounted after-tax cost incurred by the private sector in any one year is approximately $91 million in 2010.
- *2 MGD Option for new facilities and 100 MGD for Certain Waterbodies Option for existing facilities:* EPA estimates the total annualized after-tax costs of compliance to be $17.4 million (2003$). All of these direct facility costs are incurred by the private sector (including 19 manufacturing facilities and 124 offshore oil and gas extraction facilities). No facility owned by State or local governments is subject to the national requirements under this proposed option. Additionally, State and local permitting authorities are estimated to incur $0.1 million annually to administer this option, including labor costs to write permits and to conduct compliance monitoring and enforcement activities. As required per section 202 of the UMRA, EPA estimates that the highest undiscounted after-tax cost incurred by the private sector in any one year is approximately $236 million in 2011.

Thus, EPA has determined that this proposal contains a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, EPA prepared a written statement under section 202 of the UMRA, which is summarized below. (*See* Economic Analysis, Chapter D2: UMRA Analysis, for more detailed information.)

1. Summary of Written Statement

a. Authorizing Legislation

This proposal is issued under the authority of sections 101, 301, 304, 306, 308, 316, 401, 402, 501, and 510 of the Clean Water Act (CWA), 33 U.S.C. 1251, 1311, 1314, 1316, 1318, 1326, 1341, 1342, 1361, and 1370. This proposal fulfills an obligation of the U.S. Environmental Protection Agency (EPA) under a consent decree in *Riverkeeper, Inc. et al.* v. *Leavitt*, United States District Court, Southern District of New York, No. 93 Civ. 0314 (AGS). See section II of this preamble for detailed information on the legal authority of this regulation.

b. Cost-Benefit Analysis

For the analysis of costs and benefits to society of this proposal, the Agency calculated a total present value of estimated costs and benefits and then calculated the constant annual equivalent value (annualized value) of these present values. The Agency calculated these present values and annualized values using two social discount rate values: 3 percent and 7 percent. Since benefits for new offshore oil and gas extraction facilities could not be estimated, EPA's comparison of costs and benefits includes only costs associated with Phase III existing facilities (*i.e.*, the Manufacturers industry segments—no Electric Generators are subject to the national requirements under any of the co-proposed options).[58] Benefit-cost relationships for Phase III existing facilities under the three co-proposed options are as follows:[59]

- *50 MGD All Waterbodies Option:* Total annualized social costs are estimated at $47.3 (3 percent discount rate) and $50.1 million (7 percent discount rate). Total mean value of annualized use benefits are estimated at $1.9 million (3 percent discount rate) and $1.5 million (7 percent discount rate). Thus, social costs exceed total use benefits by $45.4 million (3 percent discount rate) and $48.6 million (7 percent discount rate).
- *200 MGD All Waterbodies Option:* Total annualized social costs are estimated at $22.8 (3 percent discount rate) and $24.1 million (7 percent discount rate). Total mean value of annualized use benefits are estimated at $1.3 million (3 percent discount rate) and $1.0 million (7 percent discount rate). Thus, social costs exceed total use benefits by $21.5 million (3 percent discount rate) and $23.1 million (7 percent discount rate)
- *100 MGD for Certain Waterbodies Option:* Total annualized social costs are estimated at $17.6 (3 percent discount rate) and $18.3 million (7 percent discount rate). Total mean value of annualized use benefits are estimated at $1.4 million (3 percent discount rate) and $1.1 million (7 percent discount rate). Thus, social costs exceed total use benefits by $16.2 million (3 percent discount rate) and $17.2 million (7 percent discount rate).

It should be noted that this cost-benefit analysis compares a relatively complete measure of social costs with an incomplete measure of benefits, and should be interpreted with caution. For a more detailed comparison of the costs and benefits of the proposed rule, including a qualitative discussion and ''break-even'' analysis of non-use benefits, refer to section X of this preamble.

EPA notes that States may be able to use existing sources of financial assistance to revise permits and implement the proposed options, when promulgated. Section 106 of the Clean Water Act authorizes EPA to award grants to States, Tribes, intertribal consortia, and interstate agencies for administering programs for the prevention, reduction, and elimination of water pollution. These grants may be used for various activities to develop

[57] These sections exclude facilities estimated to be baseline closures and their costs (see discussion in section VIII.B.2) and administrative costs for Federal agencies.

[58] Total social costs of this proposal, including existing and new facilities, are presented in section VIII.C of this preamble.

[59] Benefits include only use benefits from commercial and recreational fishing. EPA was unable to monetize non-use benefits.

and carry out a water pollution control program, including permitting, monitoring, and enforcement. Thus, State and Tribal NPDES permit programs represent one type of State program that can be funded by section 106 grants.

c. Macro-Economic Effects

EPA estimates that this proposal would not measurably affect the national economy, including productivity, economic growth, employment and job creation, and international competitiveness of U.S. goods and services. Macroeconomic effects on the economy are generally not considered to be measurable unless the total economic impact of a rule reaches at least 0.25 percent to 0.5 percent of Gross Domestic Product (GDP). In 2003, the Bureau of Economic Analysis reported the nominal U.S. GDP at $11.0 trillion. Thus, in order to be considered measurable, this proposal would have to generate annualized costs of at least $27 billion to $55 billion. Since EPA estimates that total social costs (including existing and new facilities) under the most costly of the three proposed options for existing facilities, the 50 MGD All Waterbodies option, would be $51 million at a 3 percent discount rate and $53 million at a 7 percent discount rate, the Agency believes that this proposal would not perceptibly affect the national economy.

d. Summary of State, Local, and Tribal Government Input

EPA consulted with State governments and representatives of local governments in developing the regulation. The outreach activities are discussed in section III of this preamble.

e. Least Burdensome Option

EPA considered and analyzed several alternative regulatory options for existing facilities to determine the best technology available for minimizing adverse environmental impact. These regulatory options are discussed in section VI of this preamble. EPA is co-proposing these three options because they would meet the requirement of section 316(b) of the CWA—that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact—and because they are economically achievable, address a large percentage of flow (in combination with the Phase II rule), are highly flexible, and impact a minimal number of small businesses. EPA believes the three co-proposed options would reflect the most cost-effective and flexible approaches among the options considered. They regulate 74 percent (50 MGD All Waterbodies Option), 45 percent (200 MGD All Waterbodies Option), and 16 percent (100 MGD for Certain Waterbodies Option), respectively, of total design intake flow potentially covered under Phase III, result in no closures, and affect only one small entity (a new offshore oil and gas facility). By providing five compliance alternatives, this proposal would offer Phase III existing facilities a high degree of flexibility in selecting the most cost-effective approach to meeting section 316(b) requirements. Under the proposal, these facilities would be able to demonstrate that existing flow or cooling water intake structure technologies fulfill section 316(b), by identifying impingement and entrainment design and control technologies, and/or use operational measures or restoration measures to fulfill the proposal's requirements. The proposal would also ensure that any applicable requirements are economically practicable through the inclusion of the site-specific compliance alternative at § 125.103(a)(5). EPA further notes that the compliance alternative specified in § 125.103(a)(4) and 125.108(a) and (b) would be included in part to provide additional flexibility to Phase III existing facilities, as well as to reduce the burden of determining, implementing, and administering section 316(b) requirements among all relevant parties. Finally, the Agency believes that the three co-proposed options would extend additional flexibility to States by providing that where a State has adopted alternative regulatory requirements that achieve environmental performance comparable to that required under the rule, the Administrator would approve such alternative requirements.

2. Impact on Small Governments

EPA has determined that this proposal would contain no regulatory requirements that might significantly or uniquely affect small governments. No government-owned facility would be subject to the national categorical requirements of the three co-proposed options.

E. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule would not have federalism implications. It would not have substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Rather, this proposed rule would result in minimal administrative costs to States that have an authorized NPDES program. Under the co-proposed 50 MGD All Waterbodies Option, EPA expects an annual burden of 16,972 hours with an annual cost of $6,823 (non-labor costs) for States to collectively administer this proposed rule. Under the co-proposed 200 MGD All Waterbodies Option, EPA expects an annual burden of 4,677 hours with an annual cost of $2,160 (non-labor costs) for States to collectively administer this proposed rule. Under the co-proposed 100 MGD Certain Waterbodies Option, EPA expects an annual burden of 6,528 hours with an annual cost of $1,973 (non-labor costs) for States to collectively administer this proposed rule. It is noted that States do not incur any burden hours and non-labor costs to administer the proposed rule for new offshore oil and gas extraction facilities since these facilities are outside of the jurisdiction of the States. EPA has identified zero Phase III existing facilities that are owned by federal, state or local government entities; therefore, the annual impacts on these facilities is zero.

The proposed national cooling water intake structure requirements would be implemented through permits issued under the NPDES program. Forty-five

States and the Virgin Islands are currently authorized pursuant to section 402(b) of the Clean Water Act to implement the NPDES program. In States not authorized to implement the NPDES program, EPA issues NPDES permits. Under the Clean Water Act, States are not required to become authorized to administer the NPDES program. Rather, such authorization is available to States if they operate their programs in a manner consistent with section 402(b) and applicable regulations. Generally, these provisions require that State NPDES programs include requirements that are as stringent as Federal program requirements. States retain the ability to implement requirements that are broader in scope or more stringent than Federal requirements. (See section 510 of the Clean Water Act.)

Today's proposed rule would not have substantial direct effects on either authorized or nonauthorized States or on local governments because it would not change how EPA and the States and local governments interact or their respective authority or responsibilities for implementing the NPDES program. Today's proposed rule would establish national requirements for Phase III facilities with cooling water intake structures. NPDES-authorized States that currently do not comply with the regulations based on today's proposal might need to amend their regulations or statutes to ensure that their NPDES programs are consistent with Federal section 316(b) requirements. See 40 CFR 123.62(e). For purposes of this proposed rule, the relationship and distribution of power and responsibilities between the Federal government and the States and local governments are established under the Clean Water Act (*e.g.*, sections 402(b) and 510); nothing in this proposed rule would alter that. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

Although section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with State governments and representatives of local governments in developing the proposed rule. During the development of the proposed and final Phase I and Phase II section 316(b) rules, EPA conducted several outreach activities through which State and local officials were informed about this proposal and they provided information and comments to the Agency. The outreach activities were intended to provide EPA with feedback on issues such as adverse environmental impact, best technology available, and the potential cost associated with various regulatory alternatives. These outreach activities are discussed in section I.C of the preamble to today's proposed rule.

In the spirit of this Executive Order and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. E.O. 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes.''

This proposed rule would not have tribal implications. It would not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes, as specified in Executive Order 13175. EPA's analyses show that no facility subject to this proposed rule is owned by tribal governments. This proposed rule would not affect Tribes in any way in the foreseeable future. Accordingly, the requirements of Executive Order 13175 do not apply to this rule.

G. E.O. 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe might have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health and safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This proposed rule is not an economically significant rule as defined under Executive Order 12866 ($100 million threshold). Further, it does not concern an environmental health or safety risk that would have a disproportionate effect on children. Therefore, it is not subject to Executive Order 13045.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This proposal is not a ''significant energy action'' as defined in Executive Order 13211, (''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Based on our analysis (see section VIII), EPA has determined that the proposal contains no compliance requirements that would:

- Reduce crude oil supply in excess of 10,000 barrels per day;
- Reduce fuel production in excess of 4,000 barrels per day;
- Reduce coal production in excess of 5 million tons per day;
- Reduce electricity production in excess of 1 billion kilowatt hours per day or in excess of 500 megawatts of installed capacity;
- Increase energy prices in excess of 10 percent;
- Increase the cost of energy distribution in excess of 10 percent;
- Significantly increase dependence on foreign supplies of energy; or
- Have other similar adverse outcomes, particularly unintended ones.

EPA analyzed the potential for impacts of the three co-proposed options and the proposed rule for new offshore oil and gas extraction facilities and found that none of them would lead to adverse outcomes. From these analyses, EPA concludes that this proposal would have minimal energy effects at a national and regional level. As a result, EPA did not prepare a Statement of Energy Effects. For more detail on the potential energy effects of this proposal, see the ''Economic Analysis for the Proposed Section 316(b) Rule for Phase III Facilities'' (DCN 7–0002). EPA requests comments on these determinations.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, Sec. 12(d) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical

standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule does not involve such technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards. EPA welcomes comments on this aspect of the proposed rule and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this proposed rule.

J. E.O. 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 requires that, to the greatest extent practicable and permitted by law, each Federal agency must make achieving environmental justice part of its mission. E.O. 12898 provides that each Federal agency must conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures such programs, policies, and activities do not have the effect of excluding persons (including populations) from participation in, denying persons (including populations) the benefits of, or subjecting persons (including populations) to discrimination under such programs, policies, and activities because of their race, color, or national origin.

Today's proposed rule would require that the location, design, construction, and capacity of cooling water intake structures at Phase III existing facilities reflect the best technology available for minimizing adverse environmental impact. For several reasons, EPA does not expect that this proposed rule would have an exclusionary effect, deny persons the benefits of the participating in a program, or subject persons to discrimination because of their race, color, or national origin.

To assess the impact of the rule on low-income and minority populations, EPA calculated the poverty rate and the percentage of the population classified as non-white for populations living within a 50-mile radius of each of the 348 (unweighted) facilities in the Phase III universe. The results of the analysis, presented in the Economic Analysis, show that the populations affected by the in-scope facilities have poverty levels and racial compositions that are quite similar to the U.S. population as a whole. Based on these results, EPA does not believe that this rule would have an exclusionary effect, deny persons the benefits of the NPDES program, or subject persons to discrimination because of their race, color, or national origin.

In fact, because EPA expects that this proposed rule would help to preserve the health of aquatic ecosystems located in reasonable proximity to Phase III existing facilities, it believes that all populations, including minority and low-income populations, would benefit from improved environmental conditions as a result of this rule.

K. E.O. 13158: Marine Protected Areas

Executive Order 13158 (65 FR 34909, May 31, 2000) requires EPA to ''expeditiously propose new science-based regulations, as necessary, to ensure appropriate levels of protection for the marine environment.'' EPA may take action to enhance or expand protection of existing marine protected areas and to establish or recommend, as appropriate, new marine protected areas. The purpose of the Executive Order is to protect the significant natural and cultural resources within the marine environment, which means ''those areas of coastal and ocean waters, the Great Lakes and their connecting waters, and submerged lands thereunder, over which the United States exercises jurisdiction, consistent with international law.''

This proposed rule recognizes the biological sensitivity of tidal rivers, estuaries, oceans, and the Great Lakes and their susceptibility to adverse environmental impact from cooling water intake structures. This proposal provides requirements for reducing both impingement and entrainment using technologies to minimize adverse environmental impact for cooling water intake structures located on these types of waterbodies.

EPA expects that this proposed rule would reduce impingement and entrainment at Phase III existing facilities. The rule would afford protection of aquatic organisms at individual, population, community, or ecosystem levels of ecological structures. Therefore, EPA expects today's proposed rule would advance the objective of the Executive Order to protect marine areas.

L. Plain Language Directive

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. We invite your comments on how to make this proposed rule easier to understand. For example: Have we organized the material to suit your needs? Are the requirements in the rule clearly stated? Does the rule contain technical language or jargon that is not clear? Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand? Would more (but shorter) sections be better? Could we improve clarity by adding tables, lists, or diagrams? What else could we do to make the rule easier to understand?

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 122

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 124

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous waste, Indians-lands, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 125

Environmental protection, Cooling water intake structure, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: November 1, 2004.

Michael O. Leavitt,

Administrator.

For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671,

21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended by revising the entry for ''122.21(r)'' and by adding entries in numerical order under the indicated heading to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB Control No.
* * * * * * *	
EPA Administered Permit Programs: The National Pollutant Discharge Elimination System	
* * * * * * *	
122.21(r)	2040–0241, 2040–0257, xxxx–xxxx
* * * * * * *	
Criteria and Standards for the National Pollutant Discharge Elimination System	
* * * * * * *	
125.103	xxxx–xxxx
125.104	xxxx–xxxx
125.106	xxxx–xxxx
125.107	xxxx–xxxx
125.108	xxxx–xxxx
* * * * * * *	

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

2. Section 122.21 is amended as follows:

a. Revising paragraph (r)(1).

b. Adding a new paragraph (r)(2)(iv).

c. Revising paragraph (r)(4) introductory text.

d. Revising paragraph (r)(5) introductory text.

§ 122.21 Application for a permit (applicable to State programs, see § 123.25)

* * * * *

(r) *Application requirements for facilities with cooling water intake structures*—(1)(i) *New facilities with new or modified cooling water intake structures.* New facilities (other than offshore oil and gas extraction facilities) with cooling water intake structures as defined in part 125, subpart I, of this chapter must submit to the Director for review the information required under paragraphs (r)(2) (except (r)(2)(iv)), (3), and (4) of this section and § 125.86 of this chapter as part of their application. New offshore oil and gas extraction facilities with cooling water intake structures as defined in part 125, subpart N, of this chapter that are fixed facilities must submit to the Director for review the information required under paragraphs (r)(2) (except (r)(2)(iv)), (3), and (4) of this section and § 125.136 of this chapter as part of their application. New offshore oil and gas extraction facilities that are *not* fixed facilities must submit to the Director for review only the information required under paragraphs (r)(2)(iv), (r)(3) (except (r)(3)(ii)), and § 125.136 of this chapter as part of their application. Requests for alternative requirements under § 125.85 or § 125.135 of this chapter must be submitted with your permit application.

(ii) *Phase II existing facilities.* Phase II existing facilities as defined in part 125, subpart J, of this chapter must submit to the Director for review the information required under paragraphs (r)(2) (except (r)(2)(iv)), (3), and (5) of this section and all applicable provisions of § 125.95 of this chapter as part of their application except for the Proposal for Information Collection which must be provided in accordance with § 125.95(b)(1).

(iii) *Phase III existing facilities.* Phase III existing facilities as defined in part 125, subpart K, of this chapter must submit to the Director for review the information required under paragraphs (r)(2) (except (r)(2)(iv)), (3), and (5) of this section and all applicable provisions of § 125.104 of this chapter as part of their application except for the Proposal for Information Collection which must be provided in accordance with § 125.104(b)(1) of this chapter.

(2) * * *

(iv) For new offshore oil and gas facilities that are *not* fixed facilities, a narrative description and/or locational maps providing information on predicted locations within the waterbody during the permit term in sufficient detail for the Director to determine the appropriateness of additional impingement requirements under § 125.134(b)(4) of this chapter.

* * * * *

(4) Source water baseline biological characterization data. This information is required to characterize the biological community in the vicinity of the cooling water intake structure and to characterize the operation of the cooling water intake structures. The Director may also use this information in subsequent permit renewal proceedings to determine if your Design and Construction Technology Plan as required in § 125.86(b)(4) or § 125.136(b)(3) of this chapter should be revised. This supporting information must include existing data (if they are available). However, you may supplement the data using newly conducted field studies if you choose to do so. The information you submit must include:

* * * * *

(5) *Cooling water system data.* Phase II and III existing facilities as defined in part 125, subparts J and K, respectively, of this chapter must provide the

following information for each cooling water intake structure they use:

* * * * *

3. Section 122.44 is amended by revising paragraph (b)(3) to read as follows:

§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).

* * * * *

(b) * * *

(3) Requirements applicable to cooling water intake structures under section 316(b) of the CWA, in accordance with part 125, subparts I, J, K, and N of this chapter.

* * * * *

PART 123—STATE PROGRAM REQUIREMENTS

1. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

2. Section 123.25 is amended by revising paragraph (a)(36) to read as follows:

§ 123.25 Requirements for permitting.

(a) * * *

(36) Subparts A, B, D, H, I, J, K, and N of part 125 of this chapter;

* * * * *

PART 124—PROCEDURES FOR DECISIONMAKING

1. The authority citation for part 124 continues to read as follows:

Authority: Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.*; Safe Drinking Water Act, 42 U.S.C. 300f *et seq.*; Clean Water Act, 33 U.S.C. 1251 *et seq.*; Clean Air Act, 42 U.S.C. 7401 *et seq.*

2. Section 124.10 is amended by revising paragraph (d)(1)(ix) to read as follows:

§ 124.10 Public notice of permit actions and public comment period.

* * * * *

(d) * * *

(1) * * *

(ix) Requirements applicable to cooling water intake structures under section 316(b) of the CWA, in accordance with part 125, subparts I , J, K, and N of this chapter.

* * * * *

PART 125—CRITERIA AND STANDARDS FOR THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

1. The authority citation for part 125 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*; unless otherwise noted.

2. Add subpart K to part 125 to read as follows:

Subpart K—Requirements Applicable to Cooling Water Intake Structures for Phase III Existing Facilities Under Section 316(b) of the Act

Sec.

125.100 What are the purpose and scope of this subpart?
125.101 What is a ''Phase III existing facility''?
125.102 What special definitions apply to this subpart?
125.103 How will requirements reflecting best technology available for minimizing adverse environmental impact be established for my Phase III existing facility?
125.104 As an owner or operator of a Phase III existing facility, what must I collect and submit when I apply for my reissued NPDES permit?
125.105 As an owner or operator of a Phase III existing facility, what monitoring must I perform?
125.106 As an owner or operator of a Phase III existing facility, what records must I keep and what information must I report?
125.107 As the Director, what must I do to comply with the requirements of this subpart?
125.108 What are Approved Design and Construction Technologies?

Subpart K—Requirements Applicable to Cooling Water Intake Structures for Phase III Existing Facilities Under Section 316(b) of the Act

§ 125.100 What are the purpose and scope of this subpart?

(a) This subpart establishes requirements that apply to the location, design, construction, and capacity of cooling water intake structures at existing facilities that are subject to this subpart (*i.e.*, Phase III existing facilities). The purpose of these requirements is to establish the best technology available for minimizing adverse environmental impact associated with the use of cooling water intake structures. These requirements are implemented through National Pollutant Discharge Elimination System (NPDES) permits issued under section 402 of the Clean Water Act (CWA).

(b) Existing facilities that are not subject to requirements under this or another subpart of this Part must meet requirements under section 316(b) of the CWA determined by the Director on a case-by-case, best professional judgment (BPJ) basis.

(c) *Alternative regulatory requirements.* Notwithstanding any other provision of this subpart, if a State demonstrates to the Administrator that it has adopted alternative regulatory requirements in its NPDES program that will result in environmental performance within a watershed that is comparable to the reductions of impingement mortality and entrainment that would otherwise be achieved under § 125.103, the Administrator must approve such alternative regulatory requirements.

(d) Nothing in this subpart shall be construed to preclude or deny the right of any State or political subdivision of a State or any interstate agency under section 510 of the CWA to adopt or enforce any requirement with respect to control or abatement of pollution that is not less stringent than those required by Federal law.

§ 125.101 What is a ''Phase III existing facility''?

OPTION A FOR PARAGRAPH (a)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 50 MGD or more, located on any waterbody type]:

(a) An existing facility, as defined in § 125.102, is a Phase III existing facility subject to this subpart if it meets each of the following criteria:

(1) It is a point source;

(2) It uses or proposes to use cooling water intake structures with a total design intake flow of 50 million gallons per day (MGD) or more to withdraw cooling water from waters of the United States;

(3) It is an existing facility other than a Phase II existing facility as defined in § 125.91 and § 125.93; and

(4) It uses at least 25 percent of water withdrawn exclusively for cooling purposes, measured on an average annual basis.

OPTION B FOR PARAGRAPH (a)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 200 MGD or more, located on any waterbody type]:

(a) An existing facility, as defined in § 125.102, is a Phase III existing facility subject to this subpart if it meets each of the following criteria:

(1) It is a point source;

(2) It uses or proposes to use cooling water intake structures with a total design intake flow of 200 million gallons per day (MGD) or more to withdraw cooling water from waters of the United States;

(3) It is an existing facility other than a Phase II existing facility as defined in § 125.91 and § 125.93; and

(4) It uses at least 25 percent of water withdrawn exclusively for cooling

purposes, measured on an average annual basis.

OPTION C FOR PARAGRAPH (a)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 100 MGD or more, located on oceans, estuaries, tidal rivers, or one of the Great Lakes]:

(a) An existing facility, as defined in § 125.102, is a Phase III existing facility subject to this subpart if it meets each of the following criteria:

(1) It is a point source;

(2) It uses or proposes to use cooling water intake structures with a total design intake flow of 100 million gallons per day (MGD) or more to withdraw cooling water from waters of the United States;

(3) It withdraws cooling water from an ocean, estuary, tidal river, or one of the Great Lakes;

(4) It is an existing facility other than a Phase II existing facility as defined in § 125.91 and § 125.93; and

(5) It uses at least 25 percent of water withdrawn exclusively for cooling purposes, measured on an average annual basis.

(b) If an existing manufacturing facility is co-located with one or more existing facilities (that are not Phase II existing facilities as defined in § 125.91 and § 125.93), each of the co-located facilities would be considered a Phase III existing facility if the combined total design intake flow of the co-located facilities is greater than the flow threshold established in paragraph (a)(2) of this section and each of the facilities meets the remaining applicability criteria in paragraph (a) of this section.

(c) Use of a cooling water intake structure includes obtaining cooling water by any sort of contract or arrangement with one or more independent suppliers of cooling water if the supplier withdraws water from waters of the United States but is not itself a Phase II existing facility (as defined in § 125.91 and § 125.93) or Phase III existing facility, except as provided in paragraph (d) of this section. This provision is intended to prevent circumvention of these requirements by creating arrangements to receive cooling water from an entity that is not itself a Phase II or Phase III existing facility.

(d) Notwithstanding paragraph (c) of this section, obtaining cooling water from a public water system or using treated effluent as cooling water at a Phase III existing facility does not constitute use of a cooling water intake structure for purposes of this subpart.

§ 125.102 What special definitions apply to this subpart?

In addition to the definitions provided in § 122.3 of this chapter, the following special definitions apply to this subpart:

Adaptive management method is a type of project management method where a facility chooses an approach to meeting the project goal, monitors the effectiveness of that approach, and then based on monitoring and any other relevant information, makes any adjustments necessary to ensure continued progress toward the project's goal. This cycle of activity is repeated as necessary to reach the project's goal.

All life stages means eggs, larvae, juveniles, and adults.

Annual mean flow means the average of daily flows over a calendar year.

Calculation baseline means an estimate of impingement mortality and entrainment that would occur at your site assuming that: the cooling water system has been designed as a once-through system; the opening of the cooling water intake structure is located at, and the face of the standard 3/8-inch mesh traveling screen is oriented parallel to, the shoreline near the surface of the source waterbody; and the baseline practices, procedures, and structural configuration are those that your facility would maintain in the absence of any structural or operational controls, including flow or velocity reductions, implemented in whole or in part for the purposes of reducing impingement mortality and entrainment. You may also choose to use the current level of impingement mortality and entrainment as the calculation baseline. The calculation baseline may be estimated using: historical impingement mortality and entrainment data from your facility or from another facility with comparable design, operational, and environmental conditions; current biological data collected in the waterbody in the vicinity of your cooling water intake structure; or current impingement mortality and entrainment data collected at your facility. You may request that the calculation baseline be modified to be based on a location of the opening of the cooling water intake structure at a depth other than at or near the surface if you can demonstrate to the Director that the other depth would correspond to a higher baseline level of impingement mortality and/or entrainment.

Closed-cycle recirculating system means a system designed, using minimized make-up and blowdown flows, to withdraw water from a natural or other water source to support contact and/or noncontact cooling uses within a facility. The water is usually sent to a cooling canal or channel, lake, pond, or tower to allow waste heat to be dissipated to the atmosphere and then is returned to the system. (Some facilities divert the waste heat to other process operations.) New source water (make-up water) is added to the system to replenish losses that have occurred due to blowdown, drift, and evaporation.

Cooling water means water used for contact or noncontact cooling, including water used for equipment cooling, evaporative cooling tower makeup, and dilution of effluent heat content. The intended use of the cooling water is to absorb waste heat rejected from the process or processes used, or from auxiliary operations on the facility's premises. Cooling water that is used in a manufacturing process either before or after it is used for cooling is considered process water for the purposes of calculating the percentage of a facility's intake flow that is used for cooling purposes in § 125.101(a)(4).

Cooling water intake structure means the total physical structure and any associated constructed waterways used to withdraw cooling water from waters of the U.S. The cooling water intake structure extends from the point at which water is withdrawn from the surface water source up to, and including, the intake pumps.

Design and construction technology means any physical configuration of the cooling water intake structure, or a technology that is placed in the water body in front of the cooling water intake structure, to reduce impingement mortality and/or entrainment. Design and construction technologies include, but are not limited to, location of the intake structure, intake screen systems, passive intake systems, fish diversion and/or avoidance systems, and fish handling and return systems. Restoration measures are not design and construction technologies for purposes of this definition.

Design intake flow means the value assigned (during the cooling water intake structure design) to the total volume of water withdrawn from a source waterbody over a specific time period.

Design intake velocity means the value assigned (during the design of a cooling water intake structure) to the average speed at which intake water passes through the open area of the intake screen (or other device) against which organisms might be impinged or through which they might be entrained.

Diel means daily and refers to variation in organism abundance and density over a 24-hour period due to the

influence of water movement, physical or chemical changes, and changes in light intensity.

Entrainment means the incorporation of any life stages of fish and shellfish with intake water flow entering and passing through a cooling water intake structure and into a cooling water system.

Estuary means a semi-enclosed body of water that has a free connection with open seas and within which the seawater is measurably diluted with fresh water derived from land drainage. The salinity of an estuary exceeds 0.5 parts per thousand (by mass) but is typically less than 30 parts per thousand (by mass).

Existing facility means any facility that commenced construction as described in 40 CFR 122.29(b)(4) on or before January 17, 2002 (or [60 days from publication of the final rule] for an offshore oil and gas extraction facility); and any modification of, or any addition of a unit at such a facility that does not meet the definition of a new facility at § 125.83.

Freshwater river or stream means a lotic (free-flowing) system that does not receive significant inflows of water from oceans or bays due to tidal action. For the purposes of this rule, a flow-through reservoir with a retention time of 7 days or less will be considered a freshwater river or stream.

Impingement means the entrapment of any life stages of fish and shellfish on the outer part of an intake structure or against a screening device during periods of intake water withdrawal.

Lake or reservoir means any inland body of open water with some minimum surface area free of rooted vegetation and with an average hydraulic retention time of more than 7 days. Lakes or reservoirs might be natural water bodies or impounded streams, usually fresh, surrounded by land or by land and a man-made retainer (*e.g.*, a dam). Lakes or reservoirs might be fed by rivers, streams, springs, and/or local precipitation.

Moribund means dying; close to death.

Natural thermal stratification means the naturally occurring and/or existing division of a waterbody into horizontal layers of differing densities as a result of variations in temperature at different depths.

Ocean means marine open coastal waters with a salinity greater than or equal to 30 parts per thousand (by mass).

Once-through cooling water system means a system designed to withdraw water from a natural or other water source, use it at the facility to support contact and/or noncontact cooling uses, and then discharge it to a waterbody without recirculation. Once-through cooling systems sometimes employ canals/channels, ponds, or non-recirculating cooling towers to dissipate waste heat from the water before it is discharged.

Operational measure means a modification to any operation at a facility that serves to minimize impact to fish and shellfish from the cooling water intake structure. Examples of operational measures include, but are not limited to: reductions in cooling water intake flow through the use of variable speed pumps and seasonal flow reductions or shutdowns; and more frequent rotation of traveling screens.

Source water means the waters of the U.S. from which the cooling water is withdrawn.

Supplier means an entity, other than the regulated facility, that owns and operates its own cooling water intake structure and directly withdraws water from waters of the United States. The supplier sells the cooling water to other facilities for their use, but may also use a portion of the water itself. An entity that provides potable water to residential populations (*e.g.*, public water system) is not a supplier for purposes of this subpart.

Thermocline means the middle layer of a thermally stratified lake or a reservoir. In this layer, there is a rapid change in temperatures between the top and bottom of the layer.

Tidal river means the most seaward reach of a river or stream where the salinity is typically less than or equal to 0.5 parts per thousand (by mass) at a time of annual low flow and whose surface elevation responds to the effects of coastal lunar tides.

§ 125.103 How will requirements reflecting best technology available for minimizing adverse environmental impact be established for my Phase III existing facility?

(a) *Compliance Alternatives.* You must select and implement one of the following five alternatives for establishing best technology available for minimizing adverse environmental impact at your facility:

(1)(i) You may demonstrate to the Director that you have reduced, or will reduce, your flow commensurate with a closed-cycle recirculating system. In this case, you are deemed to have met the applicable performance standards and will *not* be required to demonstrate further that your facility meets the impingement mortality and entrainment performance standards specified in paragraph (b) of this section. In addition, you are not subject to the requirements in §§ 125.104, 125.105, 125.106, or 125.107. However, you may still be subject to any more stringent requirements established under paragraph (e) of this section; or

(ii) You may demonstrate to the Director that you have reduced, or will reduce, your maximum through-screen design intake velocity to 0.5 ft/s or less. In this case, you are deemed to have met the impingement mortality performance standards and will *not* be required to demonstrate further that your facility meets the performance standards for impingement mortality specified in paragraph (b) of this section and you are not subject to the requirements in §§ 125.104, 125.105, 125.106, or 125.107 as they apply to impingement mortality. However, you are still subject to any applicable requirements for entrainment reduction and may still be subject to any more stringent requirements established under paragraph (e) of this section.

(2) You may demonstrate to the Director that your existing design and construction technologies, operational measures, and/or restoration measures meet the performance standards specified in paragraph (b) of this section and/or the restoration requirements in paragraph (c) of this section;

(3) You may demonstrate to the Director that you have selected, and will install and properly operate and maintain, design and construction technologies, operational measures, and/or restoration measures that will, in combination with any existing design and construction technologies, operational measures, and/or restoration measures, meet the performance standards specified in paragraph (b) of this section and/or the restoration requirements in paragraph (c) of this section;

(4) You may demonstrate to the Director that you have installed, or will install, and properly operate and maintain an approved design and construction technology in accordance with § 125.108(a) or (b); or

(5) You may demonstrate to the Director that you have selected, installed, and are properly operating and maintaining, or will install and properly operate and maintain design and construction technologies, operational measures, and/or restoration measures that the Director has determined to be the best technology available to minimize adverse environmental impact for your facility in accordance with paragraphs (a)(5)(i) or (a)(5)(ii) of this section.

(i) If the Director determines that data specific to your facility demonstrate that the costs of compliance under

alternatives in paragraphs (a)(2) through (4) of this section would be significantly greater than the costs considered by the Administrator for a facility like yours in establishing the applicable performance standards in paragraph (b) of this section, the Director must make a site-specific determination of the best technology available for minimizing adverse environmental impact. This determination must be based on reliable, scientifically valid cost and performance data submitted by you and any other information that the Director deems appropriate. The Director must establish site-specific alternative requirements based on new and/or existing design and construction technologies, operational measures, and/or restoration measures that achieve an efficacy that is, in the judgment of the Director, as close as practicable to the applicable performance standards in paragraph (b) of this section, without resulting in costs that are significantly greater than the costs considered by the Administrator for a facility like yours in establishing the applicable performance standards. The Director's site-specific determination may conclude that design and construction technologies, operational measures, and/or restoration measures in addition to those already in place are not justified because of the significantly greater costs. To calculate the costs considered by the Administrator for a facility like yours in establishing the applicable performance standards you must:

(A) Determine which technology the Administrator modeled as the most appropriate compliance technology for your facility;

(B) Using the Administrator's costing equations, calculate the annualized capital and net operation and maintenance (O&M) costs for a facility with your design intake flow using this technology;

(C) Determine the annualized net revenue loss associated with net construction downtime that the Administrator modeled for your facility to install this technology;

(D) Determine the annualized pilot study costs that the Administrator modeled for your facility to test and optimize this technology;

(E) Sum the cost items in paragraphs (a)(5)(i)(B), (a)(5)(i)(C), and (a)(5)(i)(D) of this section; and

(F) Determine if the performance standards that form the basis of these estimates (*i.e.*, impingement mortality reduction only or impingement mortality and entrainment reduction) are applicable to your facility, and if necessary, adjust the estimates to correspond to the applicable performance standards.

(ii) If the Director determines that data specific to your facility demonstrate that the costs of compliance under alternatives in paragraphs (a)(2) through (4) of this section would be significantly greater than the benefits of complying with the applicable performance standards at your facility, the Director must make a site-specific determination of best technology available for minimizing adverse environmental impact. This determination must be based on reliable, scientifically valid cost and performance data submitted by you and any other information the Director deems appropriate. The Director must establish site-specific alternative requirements based on new and/or existing design and construction technologies, operational measures, and/or restoration measures that achieve an efficacy that, in the judgment of the Director, is as close as practicable to the applicable performance standards in paragraph (b) of this section without resulting in costs that are significantly greater than the benefits at your facility. The Director's site-specific determination may conclude that design and construction technologies, operational measures, and/or restoration measures in addition to those already in place are not justified because the costs would be significantly greater than the benefits at your facility.

OPTION A FOR PARAGRAPH (b)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 50 MGD or more, located on any waterbody type or the regulatory option that defines a Phase III existing facility as one with design intake flows 200 MGD or more, located on any waterbody type]:

(b) *National Performance Standards*—(1) *Impingement Mortality Performance Standards.* If you choose compliance alternatives in paragraphs (a)(2), (a)(3), or (a)(4) of this section, you must reduce impingement mortality for all life stages of fish and shellfish by 80 to 95 percent from the calculation baseline.

(2) *Entrainment Performance Standards.* If you choose compliance alternatives in paragraphs (a)(1)(ii), (a)(2), (a)(3), or (a)(4) of this section, you must also reduce entrainment of all life stages of fish and shellfish by 60 to 90 percent from the calculation baseline if:

(i) Your facility is a Phase III existing facility; and

(ii)(A) Your facility uses cooling water withdrawn from a tidal river, estuary, ocean, or one of the Great Lakes; or

(B) Your facility uses cooling water withdrawn from a freshwater river or stream and the design intake flow of your cooling water intake structures is greater than five percent of the mean annual flow.

(3) *Additional Performance Standards for Facilities Withdrawing from a Lake (Other Than One of the Great Lakes) or a Reservoir.* If your facility withdraws cooling water from a lake (other than one of the Great Lakes) or a reservoir and you propose to increase the design intake flow of cooling water intake structures it uses, your increased design intake flow must not disrupt the natural thermal stratification or turnover pattern (where present) of the source water, except in cases where the disruption does not adversely affect the management of fisheries. In determining whether any such disruption does not adversely affect the management of fisheries, you must consult with Federal, State, or Tribal fish and wildlife management agencies.

(4) *Use of Performance Standards for Site-Specific Determinations of Best Technology Available.* The performance standards in paragraphs (b)(1) and (2) of this section must also be used for determining eligibility for site-specific determinations of best technology available for minimizing adverse environmental impact and establishing site-specific requirements that achieve an efficacy as close as practicable to the applicable performance standards without resulting in costs that are significantly greater than those considered by the Administrator for a facility like yours in establishing the performance standards or costs that are significantly greater than the benefits at your facility, pursuant to paragraph (a)(5) of this section.

OPTION B FOR PARAGRAPH (b)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 100 MGD or more, located on oceans, estuaries, tidal rivers, or one of the Great Lakes]:

(b) *National Performance Standards*—(1) *Impingement Mortality Performance Standards.* If you choose compliance alternatives in paragraphs (a)(2), (a)(3), or (a)(4) of this section, you must reduce impingement mortality for all life stages of fish and shellfish by 80 to 95 percent from the calculation baseline.

(2) *Entrainment Performance Standards.* If you choose compliance alternatives in paragraphs (a)(1)(ii), (a)(2), (a)(3), or (a)(4) of this section, you must also reduce entrainment of all life stages of fish and shellfish by 60 to 90 percent from the calculation baseline.

(3) *Use of Performance Standards for Site-Specific Determinations of Best Technology Available.* The performance standards in paragraphs (b)(1) and (2) of this section must also be used for determining eligibility for site-specific determinations of best technology available for minimizing adverse environmental impact and establishing site specific requirements that achieve an efficacy as close as practicable to the applicable performance standards without resulting in costs that are significantly greater than those considered by the Administrator for a facility like yours in establishing the performance standards or costs that are significantly greater than the benefits at your facility, pursuant to paragraph (a)(5) of this section.

(c) *Requirements for Restoration Measures.* With the approval of the Director, you may implement and adaptively manage restoration measures that produce and result in increases of fish and shellfish in your facility's watershed in place of or as a supplement to installing design and control technologies and/or adopting operational measures that reduce impingement mortality and entrainment. You must demonstrate to the Director that:

(1) You have evaluated the use of design and construction technologies and operational measures for your facility and determined that the use of restoration measures is appropriate because meeting the applicable performance standards or site-specific requirements through the use of design and construction technologies and/or operational measures alone is less feasible, less cost-effective, or less environmentally desirable than meeting the standards or requirements in whole or in part through the use of restoration measures; and

(2) The restoration measures you will implement, alone or in combination with design and construction technologies and/or operational measures, will produce ecological benefits (fish and shellfish), including maintenance or protection of community structure and function in your facility's waterbody or watershed, at a level that is substantially similar to the level you would achieve by meeting the applicable performance standards under paragraph (b) of this section, or that satisfies alternative site-specific requirements established pursuant to paragraph (a)(5) of this section.

(d)(1) *Compliance Using a Technology Installation and Operation Plan or Restoration Plan.* If you choose one of the compliance alternatives in paragraphs (a)(2), (3), (4), or (5) of this section, you may request that compliance with the requirements of paragraphs (a)(5) and (b) of this section during the first permit containing requirements consistent with this subpart be determined based on whether you have complied with the construction, operational, maintenance, monitoring, and adaptive management requirements of a Technology Installation and Operation Plan developed in accordance with § 125.104(b)(4)(ii) (for any design and construction technologies and/or operational measures) and/or a Restoration Plan developed in accordance with § 125.104(b)(5) (for any restoration measures). The Technology Installation and Operation Plan must be designed to meet applicable performance standards in paragraph (b) of this section or alternative site-specific requirements developed pursuant to paragraph (a)(5) of this section. The Restoration Plan must be designed to achieve compliance with the applicable requirements in paragraph (c) of this section.

(2) During subsequent permit terms, if you selected and installed design and construction technologies and/or operational measures and have been in compliance with the construction, operational, maintenance, monitoring, and adaptive management requirements of your Technology Installation and Operation Plan during the preceding permit term, you may request that compliance with the requirements of this section during the following permit term be determined based on whether you remain in compliance with your Technology Installation and Operation Plan, revised in accordance with your adaptive management plan in § 125.104(b)(4)(ii)(C) if applicable performance standards are not being met. Each request and approval of a Technology Installation and Operation Plan shall be limited to one permit term.

(3) During subsequent permit terms, if you selected and installed restoration measures and have been in compliance with the construction, operational, maintenance, monitoring, and adaptive management requirements in your Restoration Plan during the preceding permit term, you may request that compliance with the requirements of this section during the following permit term be determined based on whether you remain in compliance with your Restoration Plan, revised in accordance with your adaptive management plan in § 125.104(b)(5)(v) if applicable performance standards are not being met. Each request and approval of a Restoration Plan shall be limited to one permit term.

(e) *More Stringent Standards.* The Director may establish more stringent requirements as best technology available for minimizing adverse environmental impact if the Director determines that your compliance with the applicable requirements of this section would not meet the requirements of applicable State and Tribal law, or other Federal law.

§ 125.104 As an owner or operator of a Phase III existing facility, what must I collect and submit when I apply for my reissued NPDES permit?

(a)(1) You must submit to the Director the Proposal for Information Collection required in paragraph (b)(1) of this section prior to the start of information collection activities;

(2) You must submit to the Director the information required in 40 CFR 122.21(r)(2) (except (r)(2)(iv)), (r)(3) and (r)(5) and any applicable portions of the Comprehensive Demonstration Study (Study), except for the Proposal for Information Collection required by paragraph (b)(1) of this section; and

(i) You must submit your NPDES permit application in accordance with the time frames specified in 40 CFR 122.21(d)(2).

(ii) If you are a Phase III existing facility and your existing permit expires before [4 years from publication of the final rule], you may request that the Director establish a schedule for you to submit the information required by this section as expeditiously as practicable, but not later than [3 years and 180 days from publication of the final rule]. Between the time your existing permit expires and the time an NPDES permit containing requirements consistent with this subpart is issued to your facility, the best technology available to minimize adverse environmental impact will continue to be determined based on the Director's best professional judgment.

(3) In subsequent permit terms, the Director may approve a request to reduce the information required to be submitted in your permit application on the cooling water intake structure(s) and the source waterbody, if conditions at your facility and in the waterbody remain substantially unchanged since your previous application. You must submit your request for reduced cooling water intake structure and waterbody application information to the Director at least one year prior to the expiration of the permit. Your request must identify each required information item in 40 CFR 122.21(r) and this section that you determine has not substantially changed since the previous permit

application and the basis for your determination.

OPTION A FOR PARAGRAPH (b)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 50 MGD or more, located on any waterbody type or the regulatory option that defines a Phase III existing facility as one with design intake flows 200 MGD or more, located on any waterbody type]:

(b) *Comprehensive Demonstration Study* The purpose of the Comprehensive Demonstration Study (Study) is to characterize impingement mortality and entrainment, to describe the operation of your cooling water intake structures, and to confirm that the technologies, operational measures, and/or restoration measures you have selected and installed, or will install, at your facility meet the applicable requirements of § 125.103. All facilities except those that have met the applicable requirements in accordance with §§ 125.103(a)(1)(i), 125.103(a)(1)(ii), and 125.103(a)(4) must submit all applicable portions of the Comprehensive Demonstration Study to the Director in accordance with paragraph (a) of this section. Facilities that meet the requirements in § 125.103(a)(1)(i) by reducing their flow commensurate with a closed-cycle, recirculating system are not required to submit a Comprehensive Demonstration Study. Facilities that meet the requirements in § 125.103(a)(1)(ii) by reducing their design intake velocity to 0.5 ft/sec or less are required to submit a Study only for the entrainment requirements, if applicable. Facilities that meet the requirements in § 125.103(a)(4) and have installed and properly operate and maintain an approved design and construction technology (in accordance with § 125.108) are required to submit only the Technology Installation and Operation Plan in paragraph (b)(4) of this section and the Verification Monitoring Plan in paragraph (b)(7) of this section. Facilities that are required to meet only impingement mortality performance standards in § 125.103(b)(1) are required to submit only a Study for the impingement mortality reduction requirements. The Comprehensive Demonstration Study must include:

(1) *Proposal For Information Collection.* You must submit to the Director for review and comment a description of the information you will use to support your Study. The Proposal for Information Collection must be submitted prior to the start of information collection activities, but you may initiate such activities prior to receiving comment from the Director. The proposal must include:

(i) A description of the proposed and/or implemented technologies, operational measures, and/or restoration measures to be evaluated in the Study;

(ii) A list and description of any historical studies characterizing impingement mortality and entrainment and/or the physical and biological conditions in the vicinity of the cooling water intake structures and their relevance to this proposed Study. If you propose to use existing data, you must demonstrate the extent to which the data are representative of current conditions and that the data were collected using appropriate quality assurance/quality control procedures;

(iii) A summary of any past or ongoing consultations with appropriate Federal, State, and Tribal fish and wildlife agencies that are relevant to this Study and a copy of written comments received as a result of such consultations; and

(iv) A sampling plan for any new field studies you propose to conduct in order to ensure that you have sufficient data to develop a scientifically valid estimate of impingement mortality and entrainment at your site. The sampling plan must document all methods and quality assurance/quality control procedures for sampling and data analysis. The sampling and data analysis methods you propose must be appropriate for a quantitative survey and include consideration of the methods used in other studies performed in the source waterbody. The sampling plan must include a description of the study area (including the area of influence of the cooling water intake structure(s)), and provide a taxonomic identification of the sampled or evaluated biological assemblages (including all life stages of fish and shellfish).

(2) *Source Waterbody Flow Information.* You must submit to the Director the following source waterbody flow information:

(i) If your cooling water intake structure is located in a freshwater river or stream, you must provide the annual mean flow of the waterbody and any supporting documentation and engineering calculations to support your analysis of whether your design intake flow is greater than five percent of the mean annual flow of the river or stream for purposes of determining applicable performance standards under § 125.103(b). Representative historical data (from a period of time up to 10 years, if available) must be used; and

(ii) If your cooling water intake structure is located in a lake (other than one of the Great Lakes) or a reservoir and you propose to increase its design intake flow, you must provide a description of the thermal stratification in the waterbody, and any supporting documentation and engineering calculations to show that the total design intake flow after the increase will not disrupt the natural thermal stratification and turnover pattern in a way that adversely impacts fisheries, including the results of any consultations with Federal, State, or Tribal fish and wildlife management agencies.

(3) *Impingement Mortality and/or Entrainment Characterization Study.* You must submit to the Director an Impingement Mortality and/or Entrainment Characterization Study whose purpose is to provide information to support the development of a calculation baseline for evaluating impingement mortality and entrainment and to characterize current impingement mortality and entrainment. The Impingement Mortality and/or Entrainment Characterization Study must include the following, in sufficient detail to support development of the other elements of the Comprehensive Demonstration Study:

(i) Taxonomic identifications of all life stages of fish, shellfish, and any species protected under Federal, State, or Tribal Law (including threatened or endangered species) that are in the vicinity of the cooling water intake structure(s) and are susceptible to impingement and entrainment;

(ii) A characterization of all life stages of fish, shellfish, and any species protected under Federal, State, or Tribal Law (including threatened or endangered species) identified pursuant to paragraph (b)(3)(i) of this section, including a description of the abundance and temporal and spatial characteristics in the vicinity of the cooling water intake structure(s), based on sufficient data to characterize annual, seasonal, and diel variations in impingement mortality and entrainment (*e.g.*, related to climate and weather differences, spawning, feeding and water column migration). These may include historical data that are representative of the current operation of your facility and of biological conditions at the site;

(iii) Documentation of the current impingement mortality and entrainment of all life stages of fish, shellfish, and any species protected under Federal, State, or Tribal Law (including threatened or endangered species)

identified pursuant to paragraph (b)(3)(i) of this section and an estimate of impingement mortality and entrainment to be used as the calculation baseline. The documentation may include historical data that are representative of the current operation of your facility and of biological conditions at the site. Impingement mortality and entrainment samples to support the calculations required in paragraphs (b)(4)(i)(C) and (b)(5)(iii) of this section must be collected during periods of representative operational flows for the cooling water intake structure and the flows associated with the samples must be documented;

(4) *Technology and Compliance Assessment Information*—(i) *Design and Construction Technology Plan.* If you choose to use design and construction technologies and/or operational measures, in whole or in part to meet the requirements of § 125.103(a)(2) or (3), you must submit a Design and Construction Technology Plan to the Director for review and approval. The plan must explain the technologies and/or operational measures you have in place and/or have selected to meet the requirements in § 125.103. (Examples of potentially appropriate technologies may include, but are not limited to, wedgewire screens, fine mesh screens, fish handling and return systems, barrier nets, aquatic filter barrier systems, vertical and/or lateral relocation of the cooling water intake structure, and enlargement of the cooling water intake structure opening to reduce velocity. Examples of potentially appropriate operational measures may include, but are not limited to, seasonal shutdowns, reductions in flow, and continuous or more frequent rotation of traveling screens.) The plan must contain the following information:

(A) A narrative description of the design and operation of all design and construction technologies and/or operational measures (existing and proposed), including fish handling and return systems, that you have in place or will use to meet the requirements to reduce impingement mortality of those species expected to be most susceptible to impingement, and information that demonstrates the efficacy of the technologies and/or operational measures for those species;

(B) A narrative description of the design and operation of all design and construction technologies and/or operational measures (existing and proposed) that you have in place or will use to meet the requirements to reduce entrainment of those species expected to be the most susceptible to entrainment, if applicable, and information that demonstrates the efficacy of the technologies and/or operational measures for those species;

(C) Calculations of the reduction in impingement mortality and entrainment of all life stages of fish and shellfish that would be achieved by the technologies and/or operational measures you have selected based on the Impingement Mortality and/or Entrainment Characterization Study in paragraph (b)(3) of this section. In determining compliance with any requirements to reduce impingement mortality or entrainment, you must assess the total reduction in impingement mortality and entrainment against the calculation baseline determined in accordance with paragraph (b)(3) of this section. Reductions in impingement mortality and entrainment from this calculation baseline as a result of any design and construction technologies and/or operational measures already implemented at your facility should be added to the reductions expected to be achieved by any additional design and/or construction technologies and operational measures that will be implemented, and any increases in fish and shellfish within the waterbody attributable to your restoration measures. Facilities that recirculate a portion of their flow, but do not reduce flow sufficiently to satisfy the compliance option in § 125.103(a)(1)(i) may take into account the reduction in impingement mortality and entrainment associated with the reduction in flow when determining the net reduction associated with existing design and construction technologies and/or operational measures. This estimate must include a site-specific evaluation of the suitability of the technologies and/or operational measures based on the species that are found at the site, and may be determined based on representative studies (*i.e.*, studies that have been conducted at a similar facility's cooling water intake structures located in the same waterbody type with similar biological characteristics) and/or site-specific technology prototype or pilot studies; and

(D) Design and engineering calculations, drawings, and estimates prepared by a qualified professional to support the descriptions required by paragraphs (b)(4)(i)(A) and (B) of this section.

(ii) *Technology Installation and Operation Plan.* If you choose the compliance alternative in § 125.103(a)(2), (3), (4), or (5) and use design and construction technologies and/or operational measures in whole or in part to comply with the applicable requirements of § 125.103, you must submit the following information with your application for review and approval by the Director:

(A) A schedule for the installation and maintenance of any new design and construction technologies. Any downtime of generating units to accommodate installation and/or maintenance of these technologies should be scheduled to coincide with otherwise necessary downtime (*e.g.*, for repair, overhaul, or routine maintenance of the generating units) to the extent practicable. Where additional downtime is required, you may coordinate scheduling of this downtime with the North American Electric Reliability Council and/or other generators in your area to ensure that impacts to reliability and supply are minimized;

(B) List of operational and other parameters to be monitored, and the location and frequency that you will monitor them;

(C) List of activities you will undertake to ensure to the degree practicable the efficacy of installed design and construction technologies and operational measures, and your schedule for implementing them;

(D) A schedule and methodology for assessing the efficacy of any installed design and construction technologies and operational measures in meeting applicable performance standards or site-specific requirements, including an adaptive management plan for revising design and construction technologies, operational measures, operation and maintenance requirements, and/or monitoring requirements if your assessment indicates that applicable performance standards or site-specific requirements are not being met; and

(E) If you choose the compliance alternative in § 125.103(a)(4), documentation that the appropriate site conditions in § 125.108(a) or (b) exist at your facility.

(5) *Restoration Plan.* If you propose to use restoration measures, in whole or in part, to meet the applicable requirements in § 125.103, you must submit the following information with your application for review and approval by the Director. You must address species of concern identified in consultation with Federal, State, and Tribal fish and wildlife management agencies with responsibility for fisheries and wildlife potentially affected by your cooling water intake structure(s).

(i) A demonstration to the Director that you have evaluated the use of design and construction technologies and/or operational measures for your facility and an explanation of how you determined that restoration would be

more feasible, cost-effective, or environmentally desirable;

(ii) A narrative description of the design and operation of all restoration measures (existing and proposed) that you have in place or will use to produce fish and shellfish;

(iii) Quantification of the ecological benefits of the proposed restoration measures. You must use information from the Impingement Mortality and/or Entrainment Characterization Study required in paragraph (b)(3) of this section, and any other available and appropriate information, to estimate the reduction in fish and shellfish impingement mortality and/or entrainment that would be necessary for your facility to comply with § 125.103(c)(2). You must then calculate the production of fish and shellfish that you will achieve with the restoration measures you will or have already installed. You must include a discussion of the nature and magnitude of uncertainty associated with the performance of these restoration measures. You must also include a discussion of the time frame within which these ecological benefits are expected to accrue;

(iv) Design calculations, drawings, and estimates to document that your proposed restoration measures in combination with design and construction technologies and/or operational measures, or alone, will meet the requirements of § 125.103(c)(2). If the restoration measures address the same fish and shellfish species identified in the Impingement Mortality and/or Entrainment Characterization Study (in-kind restoration), you must demonstrate that the restoration measures will produce a level of these fish and shellfish substantially similar to that which would result from meeting applicable performance standards in § 125.103(b), or that they will satisfy site-specific requirements established pursuant to § 125.103(a)(5). If the restoration measures address fish and shellfish species different from those identified in the Impingement Mortality and/or Entrainment Characterization Study (out-of-kind restoration), you must demonstrate that the restoration measures produce ecological benefits substantially similar to or greater than those that would be realized through in-kind restoration. Such a demonstration should be based on a watershed approach to restoration planning and consider applicable multi-agency watershed restoration plans, site-specific peer-reviewed ecological studies, and/or consultation with appropriate Federal, State, and Tribal fish and wildlife management agencies.

(v) A plan utilizing an adaptive management method for implementing, maintaining, and demonstrating the efficacy of the restoration measures you have selected and for determining the extent to which the restoration measures, or the restoration measures in combination with design and construction technologies and operational measures, have met the applicable requirements of § 125.103(c)(2). The plan must include:

(A) A monitoring plan that includes a list of the restoration parameters that will be monitored, the frequency at which you will monitor them, and success criteria for each parameter;

(B) A list of activities you will undertake to ensure the efficacy of the restoration measures, a description of the linkages between these activities and the items in paragraph (b)(5)(v)(A) of this section, and an implementation schedule; and

(C) A process for revising the Restoration Plan as new information, including monitoring data, becomes available, if the applicable requirements under § 125.103(c)(2) are not being met.

(vi) A summary of any past or ongoing consultation with appropriate Federal, State, and Tribal fish and wildlife management agencies on your use of restoration measures including a copy of any written comments received as a result of such consultations;

(vii) If requested by the Director, a peer review of the items you submit for the Restoration Plan. You must choose the peer reviewers in consultation with the Director who may consult with EPA and Federal, State, and Tribal fish and wildlife management agencies with responsibility for fish and wildlife potentially affected by your cooling water intake structure(s). Peer reviewers must have appropriate qualifications (*e.g.*, in the fields of geology, engineering, and/or biology, *etc.*) depending upon the materials to be reviewed; and

(viii) A description of the information to be included in a biennial status report to the Director.

(6) *Information to Support Site-specific Determination of Best Technology Available for Minimizing Adverse Environmental Impact.* If you have requested a site-specific determination of best technology available for minimizing adverse environmental impact pursuant to § 125.103(a)(5)(i) because of costs significantly greater than those considered by the Administrator for a facility like yours in establishing the applicable performance standards of § 125.103(b), you are required to provide to the Director the information specified in paragraphs (b)(6)(i) and (b)(6)(iii) of this section. If you have requested a site-specific determination of best technology available for minimizing adverse environmental impact pursuant to § 125.103(a)(5)(ii) because of costs significantly greater than the benefits of meeting the applicable performance standards of § 125.103(b) at your facility, you must provide the information specified in paragraphs (b)(6)(i), (b)(6)(ii), and (b)(6)(iii) of this section:

(i) *Comprehensive Cost Evaluation Study.* You must perform and submit the results of a Comprehensive Cost Evaluation Study, that includes:

(A) Engineering cost estimates in sufficient detail to document the costs of implementing design and construction technologies, operational measures, and/or restoration measures at your facility that would be needed to meet the applicable performance standards of § 125.103(b);

(B) A demonstration that the costs documented in paragraph (b)(6)(i)(A) of this section significantly exceed either those considered by the Administrator for a facility like yours in establishing the applicable performance standards or the benefits of meeting the applicable performance standards at your facility; and

(C) Engineering cost estimates in sufficient detail to document the costs of implementing the design and construction technologies, operational measures, and/or restoration measures in your Site-Specific Technology Plan developed in accordance with paragraph (b)(6)(iii) of this section.

(ii) *Benefits Valuation Study.* If you are seeking a site-specific determination of best technology available for minimizing adverse environmental impact because of costs significantly greater than the benefits of meeting the applicable performance standards of § 125.103(b) at your facility, you must use a comprehensive methodology to fully value the impacts of impingement mortality and entrainment at your site and the benefits achievable by meeting the applicable performance standards. In addition to the valuation estimates, the benefit study must include the following:

(A) A description of the methodology(ies) used to value commercial, recreational, and ecological benefits (including any non-use benefits, if applicable);

(B) Documentation of the basis for any assumptions and quantitative estimates. If you plan to use an entrainment survival rate other than zero, you must

submit a determination of entrainment survival at your facility based on a study approved by the Director;

(C) An analysis of the effects of significant sources of uncertainty on the results of the study; and

(D) If requested by the Director, a peer review of the items you submit in the Benefits Valuation Study. You must choose the peer reviewers in consultation with the Director who may consult with EPA and Federal, State, and Tribal fish and wildlife management agencies with responsibility for fish and wildlife potentially affected by your cooling water intake structure. Peer reviewers must have appropriate qualifications depending upon the materials to be reviewed.

(E) A narrative description of any non-monetized benefits that would be realized at your site if you were to meet the applicable performance standards and a qualitative assessment of their magnitude and significance.

(iii) *Site-Specific Technology Plan.* Based on the results of the Comprehensive Cost Evaluation Study required by paragraph (b)(6)(i) of this section, and the Benefits Valuation Study required by paragraph (b)(6)(ii) of this section, if applicable, you must submit a Site-Specific Technology Plan to the Director for review and approval. The plan must contain the following information:

(A) A narrative description of the design and operation of all existing and proposed design and construction technologies, operational measures, and/or restoration measures that you have selected in accordance with § 125.103(a)(5);

(B) An engineering estimate of the efficacy of the proposed and/or implemented design and construction technologies or operational measures, and/or restoration measures. This estimate must include a site-specific evaluation of the suitability of the technologies or operational measures for reducing impingement mortality and/or entrainment (as applicable) of all life stages of fish and shellfish based on representative studies (*e.g.*, studies that have been conducted at cooling water intake structures located in the same waterbody type with similar biological characteristics) and, if applicable, site-specific technology prototype or pilot studies. If restoration measures will be used, you must provide a Restoration Plan that includes the elements described in paragraph (b)(5) of this section.

(C) A demonstration that the proposed and/or implemented design and construction technologies, operational measures, and/or restoration measures achieve an efficacy that is as close as practicable to the applicable performance standards of § 125.103(b) without resulting in costs significantly greater than either the costs considered by the Administrator for a facility like yours in establishing the applicable performance standards, or as appropriate, the benefits of complying with the applicable performance standards at your facility;

(D) Design and engineering calculations, drawings, and estimates prepared by a qualified professional to support the elements of the Plan.

(7) *Verification Monitoring Plan.* If you comply using compliance alternatives in § 125.103(a)(2), (3), (4), or (5) using design and construction technologies and/or operational measures, you must submit a plan to conduct, at a minimum, two years of monitoring to verify the full-scale performance of the proposed or already implemented technologies and/or operational measures. The verification study must begin once the design and construction technologies and/or operational measures are installed and continue for a period of time that is sufficient to demonstrate to the Director whether the facility is meeting the applicable performance standards in § 125.103(b) or site-specific requirements developed pursuant to § 125.103(a)(5). The plan must provide the following:

(i) Description of the frequency and duration of monitoring, the parameters to be monitored, and the basis for determining the parameters and the frequency and duration for monitoring. The parameters selected and duration and frequency of monitoring must be consistent with any methodology for assessing success in meeting applicable performance standards in your Technology Installation and Operation Plan as required by paragraph (b)(4)(ii) of this section.

(ii) A proposal on how naturally moribund fish and shellfish that enter the cooling water intake structure would be identified and taken into account in assessing success in meeting the performance standards in § 125.103(b) or site-specific requirements developed pursuant to § 125.103(a)(5).

(iii) A description of the information to be included in a biennial status report to the Director.

OPTION B FOR PARAGRAPH (b)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 100 MGD or more, located on oceans, estuaries, tidal rivers, or one of the Great Lakes]:

(b) *Comprehensive Demonstration Study.* The purpose of the Comprehensive Demonstration Study (Study) is to characterize impingement mortality and entrainment, to describe the operation of your cooling water intake structures, and to confirm that the technologies, operational measures, and/or restoration measures you have selected and installed, or will install, at your facility meet the applicable requirements of § 125.103. All facilities except those that have met the applicable requirements in accordance with §§ 125.103(a)(1)(i), 125.103(a)(1)(ii), and 125.103(a)(4) must submit all applicable portions of the Comprehensive Demonstration Study to the Director in accordance with paragraph (a) of this section. Facilities that meet the requirements in § 125.103(a)(1)(i) by reducing their flow commensurate with a closed-cycle, recirculating system are not required to submit a Comprehensive Demonstration Study. Facilities that meet the requirements in § 125.103(a)(1)(ii) by reducing their design intake velocity to 0.5 ft/sec or less are required to submit a Study only for the entrainment requirements. Facilities that meet the requirements in § 125.103(a)(4) and have installed and properly operate and maintain an approved design and construction technology (in accordance with § 125.108) are required to submit only the Technology Installation and Operation Plan in paragraph (b)(4) of this section and the Verification Monitoring Plan in paragraph (b)(7) of this section. The Comprehensive Demonstration Study must include:

(1) *Proposal for Information Collection.* You must submit to the Director for review and comment a description of the information you will use to support your Study. The Proposal for Information Collection must be submitted prior to the start of information collection activities, but you may initiate such activities prior to receiving comment from the Director. The proposal must include:

(i) A description of the proposed and/or implemented technologies, operational measures, and/or restoration measures to be evaluated in the Study;

(ii) A list and description of any historical studies characterizing impingement mortality and entrainment and/or the physical and biological conditions in the vicinity of the cooling water intake structures and their relevance to this proposed Study. If you propose to use existing data, you must demonstrate the extent to which the data are representative of current conditions and that the data were

collected using appropriate quality assurance/quality control procedures;

(iii) A summary of any past or ongoing consultations with appropriate Federal, State, and Tribal fish and wildlife agencies that are relevant to this Study and a copy of written comments received as a result of such consultations; and

(iv) A sampling plan for any new field studies you propose to conduct in order to ensure that you have sufficient data to develop a scientifically valid estimate of impingement mortality and entrainment at your site. The sampling plan must document all methods and quality assurance/quality control procedures for sampling and data analysis. The sampling and data analysis methods you propose must be appropriate for a quantitative survey and include consideration of the methods used in other studies performed in the source waterbody. The sampling plan must include a description of the study area (including the area of influence of the cooling water intake structure(s)), and provide a taxonomic identification of the sampled or evaluated biological assemblages (including all life stages of fish and shellfish).

(2) *Impingement Mortality and Entrainment Characterization Study.* You must submit to the Director an Impingement Mortality and Entrainment Characterization Study whose purpose is to provide information to support the development of a calculation baseline for evaluating impingement mortality and entrainment and to characterize current impingement mortality and entrainment. The Impingement Mortality and Entrainment Characterization Study must include the following, in sufficient detail to support development of the other elements of the Comprehensive Demonstration Study:

(i) Taxonomic identifications of all life stages of fish, shellfish, and any species protected under Federal, State, or Tribal Law (including threatened or endangered species) that are in the vicinity of the cooling water intake structure(s) and are susceptible to impingement and entrainment;

(ii) A characterization of all life stages of fish, shellfish, and any species protected under Federal, State, or Tribal Law (including threatened or endangered species) identified pursuant to paragraph (b)(2)(i) of this section, including a description of the abundance and temporal and spatial characteristics in the vicinity of the cooling water intake structure(s), based on sufficient data to characterize annual, seasonal, and diel variations in impingement mortality and entrainment (*e.g.*, related to climate and weather differences, spawning, feeding and water column migration). These may include historical data that are representative of the current operation of your facility and of biological conditions at the site;

(iii) Documentation of the current impingement mortality and entrainment of all life stages of fish, shellfish, and any species protected under Federal, State, or Tribal Law (including threatened or endangered species) identified pursuant to paragraph (b)(2)(i) of this section and an estimate of impingement mortality and entrainment to be used as the calculation baseline. The documentation may include historical data that are representative of the current operation of your facility and of biological conditions at the site. Impingement mortality and entrainment samples to support the calculations required in paragraphs (b)(3)(i)(C) and (b)(4)(iii) of this section must be collected during periods of representative operational flows for the cooling water intake structure and the flows associated with the samples must be documented;

(3) *Technology and Compliance Assessment Information*—(i) *Design and Construction Technology Plan.* If you choose to use design and construction technologies and/or operational measures, in whole or in part to meet the requirements of § 125.103(a)(2) or (3), you must submit a Design and Construction Technology Plan to the Director for review and approval. The plan must explain the technologies and/or operational measures you have in place and/or have selected to meet the requirements in § 125.103. (Examples of potentially appropriate technologies may include, but are not limited to, wedgewire screens, fine mesh screens, fish handling and return systems, barrier nets, aquatic filter barrier systems, vertical and/or lateral relocation of the cooling water intake structure, and enlargement of the cooling water intake structure opening to reduce velocity. Examples of potentially appropriate operational measures may include, but are not limited to, seasonal shutdowns, reductions in flow, and continuous or more frequent rotation of traveling screens.) The plan must contain the following information:

(A) A narrative description of the design and operation of all design and construction technologies and/or operational measures (existing and proposed), including fish handling and return systems, that you have in place or will use to meet the requirements to reduce impingement mortality of those species expected to be most susceptible to impingement, and information that demonstrates the efficacy of the technologies and/or operational measures for those species;

(B) A narrative description of the design and operation of all design and construction technologies and/or operational measures (existing and proposed) that you have in place or will use to meet the requirements to reduce entrainment of those species expected to be the most susceptible to entrainment and information that demonstrates the efficacy of the technologies and/or operational measures for those species;

(C) Calculations of the reduction in impingement mortality and entrainment of all life stages of fish and shellfish that would be achieved by the technologies and/or operational measures you have selected based on the Impingement Mortality and Entrainment Characterization Study in paragraph (b)(2) of this section. In determining compliance with any requirements to reduce impingement mortality and entrainment, you must assess the total reduction in impingement mortality and entrainment against the calculation baseline determined in accordance with paragraph (b)(2) of this section. Reductions in impingement mortality and entrainment from this calculation baseline as a result of any design and construction technologies and/or operational measures already implemented at your facility should be added to the reductions expected to be achieved by any additional design and/or construction technologies and operational measures that will be implemented, and any increases in fish and shellfish within the waterbody attributable to your restoration measures. Facilities that recirculate a portion of their flow, but do not reduce flow sufficiently to satisfy the compliance option in § 125.103(a)(1)(i) may take into account the reduction in impingement mortality and entrainment associated with the reduction in flow when determining the net reduction associated with existing design and construction technologies and/or operational measures. This estimate must include a site-specific evaluation of the suitability of the technologies and/or operational measures based on the species that are found at the site, and may be determined based on representative studies (*i.e.*, studies that have been conducted at a similar facility's cooling water intake structures located in the same waterbody type with similar biological characteristics) and/or site-specific technology prototype or pilot studies; and

(D) Design and engineering calculations, drawings, and estimates prepared by a qualified professional to support the descriptions required by paragraphs (b)(3)(i)(A) and (B) of this section.

(ii) *Technology Installation and Operation Plan*. If you choose the compliance alternative in § 125.103(a)(2), (3), (4), or (5) and use design and construction technologies and/or operational measures in whole or in part to comply with the applicable requirements of § 125.103, you must submit the following information with your application for review and approval by the Director:

(A) A schedule for the installation and maintenance of any new design and construction technologies. Any downtime of generating units to accommodate installation and/or maintenance of these technologies should be scheduled to coincide with otherwise necessary downtime (*e.g.*, for repair, overhaul, or routine maintenance of the generating units) to the extent practicable. Where additional downtime is required, you may coordinate scheduling of this downtime with the North American Electric Reliability Council and/or other generators in your area to ensure that impacts to reliability and supply are minimized;

(B) List of operational and other parameters to be monitored, and the location and frequency that you will monitor them;

(C) List of activities you will undertake to ensure to the degree practicable the efficacy of installed design and construction technologies and operational measures, and your schedule for implementing them;

(D) A schedule and methodology for assessing the efficacy of any installed design and construction technologies and operational measures in meeting applicable performance standards or site-specific requirements, including an adaptive management plan for revising design and construction technologies, operational measures, operation and maintenance requirements, and/or monitoring requirements if your assessment indicates that applicable performance standards or site-specific requirements are not being met; and

(E) If you choose the compliance alternative in § 125.103(a)(4), documentation that the appropriate site conditions in § 125.108(b) exist at your facility.

(4) *Restoration Plan*. If you propose to use restoration measures, in whole or in part, to meet the applicable requirements in § 125.103, you must submit the following information with your application for review and approval by the Director. You must address species of concern identified in consultation with Federal, State, and Tribal fish and wildlife management agencies with responsibility for fisheries and wildlife potentially affected by your cooling water intake structure(s).

(i) A demonstration to the Director that you have evaluated the use of design and construction technologies and/or operational measures for your facility and an explanation of how you determined that restoration would be more feasible, cost-effective, or environmentally desirable;

(ii) A narrative description of the design and operation of all restoration measures (existing and proposed) that you have in place or will use to produce fish and shellfish;

(iii) Quantification of the ecological benefits of the proposed restoration measures. You must use information from the Impingement Mortality and Entrainment Characterization Study required in paragraph (b)(2) of this section, and any other available and appropriate information, to estimate the reduction in fish and shellfish impingement mortality and entrainment that would be necessary for your facility to comply with § 125.103(c)(2). You must then calculate the production of fish and shellfish that you will achieve with the restoration measures you will or have already installed. You must include a discussion of the nature and magnitude of uncertainty associated with the performance of these restoration measures. You must also include a discussion of the time frame within which these ecological benefits are expected to accrue;

(iv) Design calculations, drawings, and estimates to document that your proposed restoration measures in combination with design and construction technologies and/or operational measures, or alone, will meet the requirements of § 125.103(c)(2). If the restoration measures address the same fish and shellfish species identified in the Impingement Mortality and Entrainment Characterization Study (in-kind restoration), you must demonstrate that the restoration measures will produce a level of these fish and shellfish substantially similar to that which would result from meeting applicable performance standards in § 125.103(b), or that they will satisfy site-specific requirements established pursuant to § 125.103(a)(5). If the restoration measures address fish and shellfish species different from those identified in the Impingement Mortality and Entrainment Characterization Study (out-of-kind restoration), you must demonstrate that the restoration measures produce ecological benefits substantially similar to or greater than those that would be realized through in-kind restoration. Such a demonstration should be based on a watershed approach to restoration planning and consider applicable multi-agency watershed restoration plans, site-specific peer-reviewed ecological studies, and/or consultation with appropriate Federal, State, and Tribal fish and wildlife management agencies.

(v) A plan utilizing an adaptive management method for implementing, maintaining, and demonstrating the efficacy of the restoration measures you have selected and for determining the extent to which the restoration measures, or the restoration measures in combination with design and construction technologies and operational measures, have met the applicable requirements of § 125.103(c)(2). The plan must include:

(A) A monitoring plan that includes a list of the restoration parameters that will be monitored, the frequency at which you will monitor them, and success criteria for each parameter;

(B) A list of activities you will undertake to ensure the efficacy of the restoration measures, a description of the linkages between these activities and the items in paragraph (b)(4)(v)(A) of this section, and an implementation schedule; and

(C) A process for revising the Restoration Plan as new information, including monitoring data, becomes available, if the applicable requirements under § 125.103(c)(2) are not being met.

(vi) A summary of any past or ongoing consultation with appropriate Federal, State, and Tribal fish and wildlife management agencies on your use of restoration measures including a copy of any written comments received as a result of such consultations;

(vii) If requested by the Director, a peer review of the items you submit for the Restoration Plan. You must choose the peer reviewers in consultation with the Director who may consult with EPA and Federal, State, and Tribal fish and wildlife management agencies with responsibility for fish and wildlife potentially affected by your cooling water intake structure(s). Peer reviewers must have appropriate qualifications (*e.g.*, in the fields of geology, engineering, and/or biology, *etc*.) depending upon the materials to be reviewed; and

(viii) A description of the information to be included in a biennial status report to the Director.

(5) *Information to Support Site-specific Determination of Best*

Technology Available for Minimizing Adverse Environmental Impact. If you have requested a site-specific determination of best technology available for minimizing adverse environmental impact pursuant to § 125.103(a)(5)(i) because of costs significantly greater than those considered by the Administrator for a facility like yours in establishing the applicable performance standards of § 125.103(b), you are required to provide to the Director the information specified in paragraphs (b)(5)(i) and (b)(5)(iii) of this section. If you have requested a site-specific determination of best technology available for minimizing adverse environmental impact pursuant to § 125.103(a)(5)(ii) because of costs significantly greater than the benefits of meeting the applicable performance standards of § 125.103(b) at your facility, you must provide the information specified in paragraphs (b)(5)(i), (b)(5)(ii), and (b)(5)(iii) of this section:

(i) *Comprehensive Cost Evaluation Study.* You must perform and submit the results of a Comprehensive Cost Evaluation Study, that includes:

(A) Engineering cost estimates in sufficient detail to document the costs of implementing design and construction technologies, operational measures, and/or restoration measures at your facility that would be needed to meet the applicable performance standards of § 125.103(b);

(B) A demonstration that the costs documented in paragraph (b)(5)(i)(A) of this section significantly exceed either those considered by the Administrator for a facility like yours in establishing the applicable performance standards or the benefits of meeting the applicable performance standards at your facility; and

(C) Engineering cost estimates in sufficient detail to document the costs of implementing the design and construction technologies, operational measures, and/or restoration measures in your Site-Specific Technology Plan developed in accordance with paragraph (b)(5)(iii) of this section.

(ii) *Benefits Valuation Study.* If you are seeking a site-specific determination of best technology available for minimizing adverse environmental impact because of costs significantly greater than the benefits of meeting the applicable performance standards of § 125.103(b) at your facility, you must use a comprehensive methodology to fully value the impacts of impingement mortality and entrainment at your site and the benefits achievable by meeting the applicable performance standards. In addition to the valuation estimates, the benefit study must include the following:

(A) A description of the methodology(ies) used to value commercial, recreational, and ecological benefits (including any non-use benefits, if applicable);

(B) Documentation of the basis for any assumptions and quantitative estimates. If you plan to use an entrainment survival rate other than zero, you must submit a determination of entrainment survival at your facility based on a study approved by the Director;

(C) An analysis of the effects of significant sources of uncertainty on the results of the study; and

(D) If requested by the Director, a peer review of the items you submit in the Benefits Valuation Study. You must choose the peer reviewers in consultation with the Director who may consult with EPA and Federal, State, and Tribal fish and wildlife management agencies with responsibility for fish and wildlife potentially affected by your cooling water intake structure. Peer reviewers must have appropriate qualifications depending upon the materials to be reviewed.

(E) A narrative description of any non-monetized benefits that would be realized at your site if you were to meet the applicable performance standards and a qualitative assessment of their magnitude and significance.

(iii) *Site-Specific Technology Plan.* Based on the results of the Comprehensive Cost Evaluation Study required by paragraph (b)(5)(i) of this section, and the Benefits Valuation Study required by paragraph (b)(5)(ii) of this section, if applicable, you must submit a Site-Specific Technology Plan to the Director for review and approval. The plan must contain the following information:

(A) A narrative description of the design and operation of all existing and proposed design and construction technologies, operational measures, and/or restoration measures that you have selected in accordance with § 125.103(a)(5);

(B) An engineering estimate of the efficacy of the proposed and/or implemented design and construction technologies or operational measures, and/or restoration measures. This estimate must include a site-specific evaluation of the suitability of the technologies or operational measures for reducing impingement mortality and entrainment of all life stages of fish and shellfish based on representative studies (*e.g.*, studies that have been conducted at cooling water intake structures located in the same waterbody type with similar biological characteristics) and, if applicable, site-specific technology prototype or pilot studies. If restoration measures will be used, you must provide a Restoration Plan that includes the elements described in paragraph (b)(4) of this section.

(C) A demonstration that the proposed and/or implemented design and construction technologies, operational measures, and/or restoration measures achieve an efficacy that is as close as practicable to the applicable performance standards of § 125.103(b) without resulting in costs significantly greater than either the costs considered by the Administrator for a facility like yours in establishing the applicable performance standards, or as appropriate, the benefits of complying with the applicable performance standards at your facility;

(D) Design and engineering calculations, drawings, and estimates prepared by a qualified professional to support the elements of the Plan.

(6) *Verification Monitoring Plan.* If you comply using compliance alternatives in § 125.103(a)(2), (3), (4), or (5) using design and construction technologies and/or operational measures, you must submit a plan to conduct, at a minimum, two years of monitoring to verify the full-scale performance of the proposed or already implemented technologies and/or operational measures. The verification study must begin once the design and construction technologies and/or operational measures are installed and continue for a period of time that is sufficient to demonstrate to the Director whether the facility is meeting the applicable performance standards in § 125.103(b) or site-specific requirements developed pursuant to § 125.103(a)(5). The plan must provide the following:

(i) Description of the frequency and duration of monitoring, the parameters to be monitored, and the basis for determining the parameters and the frequency and duration for monitoring. The parameters selected and duration and frequency of monitoring must be consistent with any methodology for assessing success in meeting applicable performance standards in your Technology Installation and Operation Plan as required by paragraph (b)(3)(ii) of this section.

(ii) A proposal on how naturally moribund fish and shellfish that enter the cooling water intake structure would be identified and taken into account in assessing success in meeting the performance standards in § 125.103(b).

(iii) A description of the information to be included in a biennial status report to the Director.

§ 125.105 As an owner or operator of a Phase III existing facility, what monitoring must I perform?

OPTION A FOR § 125.105—[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 50 MGD or more, located on any waterbody type or the regulatory option that defines a Phase III existing facility as one with design intake flows 200 MGD or more, located on any waterbody type]:

As an owner or operator of a Phase III existing facility, you must perform monitoring, as applicable, in accordance with the Technology Installation and Operation Plan required by § 125.104(b)(4)(ii), the Restoration Plan required by § 125.104(b)(5), the Verification Monitoring Plan required by § 125.104(b)(7), and any additional monitoring specified by the Director to demonstrate compliance with the applicable requirements of § 125.103.

OPTION B FOR § 125.105—[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 100 MGD or more, located on oceans, estuaries, tidal rivers, or one of the Great Lakes]:

As an owner or operator of a Phase III existing facility, you must perform monitoring, as applicable, in accordance with the Technology Installation and Operation Plan required by § 125.104(b)(3)(ii), the Restoration Plan required by § 125.104(b)(4), the Verification Monitoring Plan required by § 125.104(b)(6), and any additional monitoring specified by the Director to demonstrate compliance with the applicable requirements of § 125.103.

§ 125.106 As an owner or operator of a Phase III existing facility, what records must I keep and what information must I report?

As an owner or operator of a Phase III existing facility you are required to keep records and report information and data to the Director as follows:

(a) You must keep records of all the data used to complete the permit application and show compliance with the requirements of § 125.103, any supplemental information developed under § 125.104, and any compliance monitoring data submitted under § 125.105, for a period of at least three (3) years from date of permit issuance. The Director may require that these records be kept for a longer period.

(b) You must submit a status report to the Director for review every two years that includes appropriate monitoring data and other information as specified by the Director in accordance with § 125.107(b)(5).

§ 125.107 As the Director, what must I do to comply with the requirements of this subpart?

(a) *Permit Application.* As the Director, you must review materials submitted by the applicant under 40 CFR 122.21(r) and § 125.104 before each permit renewal or reissuance.

(1) You must review and comment on the Proposal for Information Collection submitted by the facility in accordance with § 125.104(a)(1). You are encouraged to provide comments expeditiously so that the permit applicant can make responsive modifications to its information gathering activities. If a facility submits a request in accordance with § 125.104(a)(2)(ii) for an alternate schedule for submitting the information required in § 125.104, you must approve a schedule that is as expeditious as practicable, but does not extend beyond [3 years and 180 days from publication of the final rule] for Phase III existing facilities. If a facility submits a request in accordance with § 125.104(a)(3) to reduce the information about their cooling water intake structures and the source waterbody required to be submitted in their permit application (other than with the first permit application [60 days from publication of the final rule] for Phase III existing facilities), you must approve the request within 60 days if conditions at the facility and in the waterbody remain substantially unchanged since the previous application.

(2) After receiving the permit application from the owner or operator of a Phase III existing facility, you must determine which of the requirements specified in § 125.103 apply to the facility. In addition, you must review materials to determine compliance with the applicable requirements.

(3) At each permit renewal, you must review the application materials and monitoring data to determine whether new or revised requirements for design and construction technologies, operational measures, or restoration measures should be included in the permit to meet the applicable performance standards in § 125.103(b) or alternative site-specific requirements established pursuant to § 125.103(a)(5).

OPTION A FOR PARAGRAPH (b)—[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 50 MGD or more, located on any waterbody type or the regulatory option that defines a Phase III existing facility as one with design intake flows 200 MGD or more, located on any waterbody type]:

(b) *Permitting Requirements.* Section 316(b) requirements are implemented for a facility through an NPDES permit. As the Director, you must consider the information submitted by the Phase III existing facility in its permit application, and determine the appropriate requirements and conditions to include in the permit based on the compliance alternatives in § 125.103(a). The following requirements must be included in each permit:

(1) *Cooling Water Intake Structure Requirements.* The permit conditions must include the requirements that implement the applicable provisions of § 125.103. You must evaluate the performance of the design and construction technologies, operational measures, and/or restoration measures proposed and implemented by the facility and require additional or different design and construction technologies, operational measure, and/or restoration measures, and/or improved operation and maintenance of existing technologies and measures, if needed to meet the applicable performance standards, restoration requirements, or alternative site-specific requirements. In determining compliance with the performance standards for facilities proposing to increase withdrawals of cooling water from a lake (other than a Great Lake) or a reservoir in § 125.103(b)(3), you must consider anthropogenic factors (those not considered ''natural'') unrelated to the Phase III existing facility's cooling water intake structures that can influence the occurrence and location of a thermocline. These include source water inflows, other water withdrawals, managed water uses, wastewater discharges, and flow/level management practices (*e.g.*, some reservoirs release water from deeper bottom layers). As the Director, you must coordinate with appropriate Federal, State, or Tribal fish and wildlife management agencies to determine if any disruption of the natural thermal stratification resulting from the proposed increased withdrawal of cooling water does not adversely affect the management of fisheries. Specifically:

(i) You must review and approve the Design and Construction Technology Plan required in § 125.104(b)(4) to evaluate the suitability and feasibility of the design and construction technology and/or operational measures proposed to meet the performance standards in

§ 125.103(b) or site-specific requirements developed pursuant to § 125.103(a)(5).

(ii) If the facility proposes restoration measures in accordance with § 125.103(c), you must review and approve the Restoration Plan required under § 125.104(b)(5) to determine whether the proposed measures, alone or in combination with design and construction technologies and/or operational measures, will meet the requirements under § 125.103(c).

(iii) In each reissued permit, you must include a condition in the permit requiring the facility to reduce impingement mortality and entrainment (or to increase fish production, if applicable) commensurate with the efficacy at the facility of the installed design and construction technologies, operational measures, and/or restoration measures.

(iv) If the facility implements design and construction technologies and/or operational measures and requests that compliance with the requirements in § 125.103 be measured for the first permit term (or subsequent permit terms, if applicable) employing the Technology Installation and Operation Plan in accordance with § 125.104(b)(4)(ii), you must review the Technology Installation and Operation Plan to ensure it meets the requirements of § 125.104(b)(4)(ii). If the Technology Installation and Operation Plan meets the requirements of § 125.104(b)(4)(ii), you must approve the Technology Installation and Operation Plan and require the facility to meet the terms of the plan including any revision to the plan that may be necessary if applicable performance standards or alternative site-specific requirements are not being met. If the facility implements restoration measures and requests that compliance with the requirements in § 125.103 be measured for the first permit term (or subsequent permit terms, if applicable) employing a Restoration Plan in accordance with § 125.104(b)(5), you must review the Restoration Plan to ensure it meets the requirements of § 125.104(b)(5). If the Restoration Plan meets the requirements of § 125.104(b)(5), you must approve the plan and require the facility to meet the terms of the plan including any revision to the plan that may be necessary if applicable performance standards or site-specific requirements are not being met. In determining whether to approve a Technology Installation and Operation Plan or Restoration Plan, you must evaluate whether the design and construction technologies, operational measures, and/or restoration measures the facility has installed, or proposes to install, can reasonably be expected to meet the applicable performance standards in § 125.103(b), restoration requirements in § 125.103(c)(2), and/or alternative site-specific requirements established pursuant to § 125.103(a)(5), and whether the Technology Installation and Operation Plan and/or Restoration Plan complies with the applicable requirements of § 125.104(b). In reviewing the Technology Installation and Operation Plan, you must approve any reasonable scheduling provisions that are designed to ensure that impacts to energy reliability and supply are minimized, in accordance with § 125.104(b)(4)(ii)(A). If the facility does not request that compliance with the requirements in § 125.103 be measured employing a Technology Installation and Operation Plan and/or Restoration Plan, or the facility has not been in compliance with the terms of its current Technology Installation and Operation Plan and/or Restoration Plan during the preceding permit term, you must require the facility to comply with the applicable performance standards in § 125.103(b), restoration requirement in § 125.103(c)(2), and/or alternative site-specific requirements developed pursuant to § 125.103(a)(5). In considering a permit application, you must review the performance of the design and construction technologies, operational measures, and/or restoration measures implemented and require additional or different design and construction technologies, operational measures, and/or restoration measures, and/or improved operation and maintenance of existing technologies and measures, if needed to meet the applicable performance standards, restoration requirements, and/or alternative site-specific requirements.

(v) You must review and approve the proposed Verification Monitoring Plan submitted under § 125.104(b)(7) (for design and construction technologies) and/or monitoring provisions of the Restoration Plan submitted under § 125.104(b)(5)(v) and require that the monitoring continue for a sufficient period of time to demonstrate whether the design and construction technology, operational measures, and/or restoration measures meet the applicable performance standards in § 125.103(b), restoration requirements in § 125.103(c)(2) and/or site-specific requirements established pursuant to § 125.103(a)(5).

(vi) If a facility requests requirements based on a site-specific determination of best technology available for minimizing adverse environmental impact, you must review the application materials submitted under § 125.104(b)(6) and any other information you may have, including quantitative and qualitative benefits, that would be relevant to a determination of whether alternative requirements are appropriate for the facility. If a facility submits a study to support entrainment survival at the facility, you must review and approve the results of that study. If you determine that alternative requirements are appropriate, you must make a site-specific determination of best technology available for minimizing adverse environmental impact in accordance with § 125.103(a)(5). You, as the Director, may request revisions to the information submitted by the facility in accordance with § 125.104(b)(6) if it does not provide an adequate basis for you to make this determination. Any alternative site-specific requirements established based on new and/or existing design and construction technologies, operational measures, and/or restoration measures, must achieve an efficacy that is, in your judgment, as close as practicable to the applicable performance standards of § 125.103(b) without resulting in costs that are significantly greater than the costs considered by the Administrator for a like facility in establishing the applicable performance standards in § 125.103(b), determined in accordance with § 125.103(a)(5)(i)(A) through (F), or the benefits of complying with the applicable performance standards at the facility. A ''like facility'' is one that is subject to the same requirements as those that would otherwise be applicable to the facility seeking a site-specific determination. In other words, ''like facilities'' for Phase III existing facilities include only other Phase III existing facilities; and

(vii) You must review the proposed methods for assessing success in meeting applicable performance standards and/or restoration requirements submitted by the facility under § 125.104(b)(4)(ii)(D) and/or (b)(5)(v)(A), evaluate those and other available methods, and specify how assessment of success in meeting the performance standards and/or restoration requirements must be determined including the averaging period for determining the percent reduction in impingement mortality and entrainment and/or the production of fish and shellfish. Compliance for facilities who request that compliance be measured employing a Technology Installation and Operation Plan and/or Restoration Plan must be determined in accordance with § 125.107(b)(1)(iv).

(2) *Monitoring Conditions.* You must require the facility to perform

monitoring in accordance with the Technology Installation and Operation Plan in § 125.104(b)(4)(ii), the Restoration Plan required by § 125.104(b)(5), if applicable, and the Verification Monitoring Plan required by § 125.104(b)(7). In determining any additional applicable monitoring requirements in accordance with § 125.105, you must consider the facility's Verification Monitoring, Technology Installation and Operation, and/or Restoration Plans, as appropriate. You may modify the monitoring program based on changes in physical or biological conditions in the vicinity of the cooling water intake structure.

(3) *Record Keeping and Reporting.* At a minimum, the permit must require the facility to report and keep records specified in § 125.106.

(4) *Design and Construction Technology Approval.* (i) For a facility that chooses to demonstrate that it has installed and properly operate and maintain a design and construction technology approved in accordance with § 125.108, the Director must review and approve the information submitted in the Technology Installation and Operation Plan in § 125.104(b)(4)(ii) and determine if it meets the criteria in § 125.108.

(ii) If a person requests approval of a technology under § 125.108(b), the Director must review and approve the information submitted and determine its suitability for widespread use at facilities with similar site conditions in its jurisdiction with minimal study. As the Director, you must evaluate the adequacy of the technology when installed in accordance with the required design criteria and site conditions to consistently meet the performance standards in § 125.103. You, as the Director, may only approve a technology following public notice and consideration of comment regarding such approval.

(5) *Biennial Status Report.* You must specify monitoring data and other information to be included in a status report every two years. The other information may include operation and maintenance records, summaries of adaptive management activities, or any other information that is relevant to determining compliance with the terms of the facility's Technology Operation and Installation Plan and/or Restoration Plan.

OPTION B FOR PARAGRAPH (b)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 100 MGD or more, located on oceans, estuaries, tidal rivers, or one of the Great Lakes]:

(b) *Permitting Requirements.* Section 316(b) requirements are implemented for a facility through an NPDES permit. As the Director, you must consider the information submitted by the Phase III existing facility in its permit application, and determine the appropriate requirements and conditions to include in the permit based on the compliance alternatives in § 125.103(a). The following requirements must be included in each permit:

(1) *Cooling Water Intake Structure Requirements.* The permit conditions must include the requirements that implement the applicable provisions of § 125.103. You must evaluate the performance of the design and construction technologies, operational measures, and/or restoration measures proposed and implemented by the facility and require additional or different design and construction technologies, operational measure, and/or restoration measures, and/or improved operation and maintenance of existing technologies and measures, if needed to meet the applicable performance standards, restoration requirements, or alternative site-specific requirements. Specifically:

(i) You must review and approve the Design and Construction Technology Plan required in § 125.104(b)(3) to evaluate the suitability and feasibility of the design and construction technology and/or operational measures proposed to meet the performance standards in § 125.103(b) or site-specific requirements developed pursuant to § 125.103(a)(5).

(ii) If the facility proposes restoration measures in accordance with § 125.103(c), you must review and approve the Restoration Plan required under § 125.104(b)(4) to determine whether the proposed measures, alone or in combination with design and construction technologies and/or operational measures, will meet the requirements under § 125.103(c).

(iii) In each reissued permit, you must include a condition in the permit requiring the facility to reduce impingement mortality and entrainment (or to increase fish production, if applicable) commensurate with the efficacy at the facility of the installed design and construction technologies, operational measures, and/or restoration measures.

(iv) If the facility implements design and construction technologies and/or operational measures and requests that compliance with the requirements in § 125.103 be measured for the first permit term (or subsequent permit terms, if applicable) employing the Technology Installation and Operation Plan in accordance with § 125.104(b)(3)(ii), you must review the Technology Installation and Operation Plan to ensure it meets the requirements of § 125.104(b)(3)(ii). If the Technology Installation and Operation Plan meets the requirements of § 125.104(b)(3)(ii), you must approve the Technology Installation and Operation Plan and require the facility to meet the terms of the plan including any revision to the plan that may be necessary if applicable performance standards or alternative site-specific requirements are not being met. If the facility implements restoration measures and requests that compliance with the requirements in § 125.103 be measured for the first permit term (or subsequent permit terms, if applicable) employing a Restoration Plan in accordance with § 125.104(b)(4), you must review the Restoration Plan to ensure it meets the requirements of § 125.104(b)(4). If the Restoration Plan meets the requirements of § 125.104(b)(4), you must approve the plan and require the facility to meet the terms of the plan including any revision to the plan that may be necessary if applicable performance standards or site-specific requirements are not being met. In determining whether to approve a Technology Installation and Operation Plan or Restoration Plan, you must evaluate whether the design and construction technologies, operational measures, and/or restoration measures the facility has installed, or proposes to install, can reasonably be expected to meet the applicable performance standards in § 125.103(b), restoration requirements in § 125.103(c)(2), and/or alternative site-specific requirements established pursuant to § 125.103(a)(5), and whether the Technology Installation and Operation Plan and/or Restoration Plan complies with the applicable requirements of § 125.104(b). In reviewing the Technology Installation and Operation Plan, you must approve any reasonable scheduling provisions that are designed to ensure that impacts to energy reliability and supply are minimized, in accordance with § 125.104(b)(3)(ii)(A). If the facility does not request that compliance with the requirements in § 125.103 be measured employing a Technology Installation and Operation Plan and/or Restoration Plan, or the facility has not been in compliance with the terms of its current Technology Installation and Operation Plan and/or Restoration Plan during the preceding permit term, you must require

the facility to comply with the applicable performance standards in § 125.103(b), restoration requirement in § 125.103(c)(2), and/or alternative site-specific requirements developed pursuant to § 125.103(a)(5). In considering a permit application, you must review the performance of the design and construction technologies, operational measures, and/or restoration measures implemented and require additional or different design and construction technologies, operational measures, and/or restoration measures, and/or improved operation and maintenance of existing technologies and measures, if needed to meet the applicable performance standards, restoration requirements, and/or alternative site-specific requirements.

(v) You must review and approve the proposed Verification Monitoring Plan submitted under § 125.104(b)(6) (for design and construction technologies) and/or monitoring provisions of the Restoration Plan submitted under § 125.104(b)(4)(v) and require that the monitoring continue for a sufficient period of time to demonstrate whether the design and construction technology, operational measures, and/or restoration measures meet the applicable performance standards in § 125.103(b), restoration requirements in § 125.103(c)(2) and/or site-specific requirements established pursuant to § 125.103(a)(5).

(vi) If a facility requests requirements based on a site-specific determination of best technology available for minimizing adverse environmental impact, you must review the application materials submitted under § 125.104(b)(5) and any other information you may have, including quantitative and qualitative benefits, that would be relevant to a determination of whether alternative requirements are appropriate for the facility. If a facility submits a study to support entrainment survival at the facility, you must review and approve the results of that study. If you determine that alternative requirements are appropriate, you must make a site-specific determination of best technology available for minimizing adverse environmental impact in accordance with § 125.103(a)(5). You, as the Director, may request revisions to the information submitted by the facility in accordance with § 125.104(b)(5) if it does not provide an adequate basis for you to make this determination. Any alternative site-specific requirements established based on new and/or existing design and construction technologies, operational measures, and/or restoration measures, must achieve an efficacy that is, in your judgment, as close as practicable to the applicable performance standards of § 125.103(b) without resulting in costs that are significantly greater than the costs considered by the Administrator for a like facility in establishing the applicable performance standards in § 125.103(b), determined in accordance with § 125.103(a)(5)(i)(A) through (F), or the benefits of complying with the applicable performance standards at the facility. A ''like facility'' is one that is subject to the same requirements as those that would otherwise be applicable to the facility seeking a site-specific determination. In other words, ''like facilities'' for Phase III existing facilities include only other Phase III existing facilities; and

(vii) You must review the proposed methods for assessing success in meeting applicable performance standards and/or restoration requirements submitted by the facility under § 125.104(b)(3)(ii)(D) and/or (b)(4)(v)(A), evaluate those and other available methods, and specify how assessment of success in meeting the performance standards and/or restoration requirements must be determined including the averaging period for determining the percent reduction in impingement mortality and entrainment and/or the production of fish and shellfish. Compliance for facilities who request that compliance be measured employing a Technology Installation and Operation Plan and/or Restoration Plan must be determined in accordance with § 125.107(b)(1)(iv).

(2) *Monitoring Conditions.* You must require the facility to perform monitoring in accordance with the Technology Installation and Operation Plan in § 125.104(b)(3)(ii), the Restoration Plan required by § 125.104(b)(4), if applicable, and the Verification Monitoring Plan required by § 125.104(b)(6). In determining any additional applicable monitoring requirements in accordance with § 125.105, you must consider the monitoring facility's Verification Monitoring, Technology Installation and Operation, and/or Restoration Plans, as appropriate. You may modify the monitoring program based on changes in physical or biological conditions in the vicinity of the cooling water intake structure.

(3) *Record Keeping and Reporting.* At a minimum, the permit must require the facility to report and keep records specified in § 125.106.

(4) *Design and Construction Technology Approval.* (i) For a facility that chooses to demonstrate that it has installed and properly operate and maintain a design and construction technology approved in accordance with § 125.108, the Director must review and approve the information submitted in the Technology Installation and Operation Plan in § 125.104(b)(3)(ii) and determine if it meets the criteria in § 125.108.

(ii) If a person requests approval of a technology under § 125.108(b), the Director must review and approve the information submitted and determine its suitability for widespread use at facilities with similar site conditions in its jurisdiction with minimal study. As the Director, you must evaluate the adequacy of the technology when installed in accordance with the required design criteria and site conditions to consistently meet the performance standards in § 125.103. You, as the Director, may only approve a technology following public notice and consideration of comment regarding such approval.

(5) *Biennial Status Report.* You must specify monitoring data and other information to be included in a status report every two years. The other information may include operation and maintenance records, summaries of adaptive management activities, or any other information that is relevant to determining compliance with the terms of the facility's Technology Operation and Installation Plan and/or Restoration Plan.

§ 125.108 What are Approved Design and Construction Technologies?

OPTION A FOR PARAGRAPH (a)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 50 MGD or more, located on any waterbody type or the regulatory option that defines a Phase III existing facility as one with design intake flows 200 MGD or more, located on any waterbody type]:

(a) The following technologies constitute approved design and construction technologies for purposes of § 125.103(a)(4):

(1) Submerged cylindrical wedgewire screen technology, if you meet the following conditions:

(i) Your cooling water intake structure is located in a freshwater river or stream;

(ii) Your cooling water intake structure is situated such that sufficient ambient counter currents exist to promote cleaning of the screen face;

(iii) Your maximum through-screen design intake velocity is 0.5 ft/s or less;

(iv) The slot size is appropriate for the size of eggs, larvae, and juveniles of all

fish and shellfish to be protected at the site; and

(v) Your entire main cooling water intake flow is directed through the technology. Small flows totaling less than 2 MGD for auxiliary cooling uses are excluded from this provision.

(2) A technology that has been approved in accordance with the process described in paragraph (b) of this section.

OPTION B FOR PARAGRAPH (a)—

[This language reflects the regulatory option that defines a Phase III existing facility as one with design intake flows of 100 MGD or more, located on oceans, estuaries, tidal rivers, or one of the Great Lakes]:

(a) A design and construction technology may be approved for use in accordance with the compliance alternative in § 125.103(a)(4). The technology must be approved in accordance with the process described in paragraph (b) of this section.

(b) You or any other interested person may submit a request to the Director that a technology be approved in accordance with the compliance alternative in § 125.103(a)(4) after providing the public with notice and an opportunity to comment on the request for approval of the technology. If the Director approves the technology, it may be used by all facilities with similar site conditions under the Director's jurisdiction. Requests for approval of a technology must be submitted to the Director and include the following information:

(1) A detailed description of the technology;

(2) A list of design criteria for the technology and site characteristics and conditions that each facility must have in order to ensure that the technology can consistently meet the appropriate impingement mortality and entrainment performance standards in § 125.103(b); and

(3) Information and data sufficient to demonstrate that facilities under the jurisdiction of the Director can meet the applicable impingement mortality and entrainment performance standards in § 125.103(b) if the applicable design criteria and site characteristics and conditions are present at the facility.

3. Add subpart N to part 125 to read as follows:

Subpart N—Requirements Applicable to Cooling Water Intake Structures for New Offshore Oil and Gas Extraction Facilities Under Section 316(b) of the Act

Sec.

125.130 What are the purpose and scope of this subpart?
125.131 Who is subject to this subpart?
125.132 When must I comply with this subpart?
125.133 What special definitions apply to this subpart?
125.134 As an owner or operator of a new offshore oil and gas extraction facility, what must I do to comply with this subpart?
125.135 May alternative requirements be authorized?
125.136 As an owner or operator of a new offshore oil and gas extraction facility, what must I collect and submit when I apply for my new or reissued NPDES permit?
125.137 As an owner or operator of a new offshore oil and gas extraction facility, must I perform monitoring?
125.138 As an owner or operator of a new offshore oil and gas extraction facility, must I keep records and report?
125.139 As the Director, what must I do to comply with the requirements of this subpart?

Subpart N—Requirements Applicable to Cooling Water Intake Structures for New Offshore Oil and Gas Extraction Facilities Under Section 316(b) of the Act

§ 125.130 What are the purpose and scope of this subpart?

(a) This subpart establishes requirements that apply to the location, design, construction, and capacity of cooling water intake structures at new offshore oil and gas extraction facilities. The purpose of these requirements is to establish the best technology available for minimizing adverse environmental impact associated with the use of cooling water intake structures at these facilities. These requirements are implemented through National Pollutant Discharge Elimination System (NPDES) permits issued under section 402 of the Clean Water Act (CWA).

(b) This subpart implements section 316(b) of the CWA for new offshore oil and gas extraction facilities. Section 316(b) of the CWA provides that any standard established pursuant to sections 301 or 306 of the CWA and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact.

(c) New offshore oil and gas extraction facilities that do not meet the threshold requirements regarding amount of water withdrawn or percentage of water withdrawn for cooling water purposes in § 125.131(a) must meet requirements determined by the Director on a case-by-case, best professional judgement (BPJ) basis.

(d) Nothing in this subpart shall be construed to preclude or deny the right of any State or political subdivision of a State or any interstate agency under section 510 of the CWA to adopt or enforce any requirement with respect to control or abatement of pollution that is more stringent than those required by Federal law.

§ 125.131 Who is subject to this subpart?

(a) This subpart applies to a new offshore oil and gas extraction facility if it meets all of the following criteria:

(1) It is a point source that uses or proposes to use a cooling water intake structure;

(2) It has at least one cooling water intake structure that uses at least 25 percent of the water it withdraws for cooling purposes as specified in paragraph (c) of this section; and

(3) It has a design intake flow greater than two (2) million gallons per day (MGD).

(b) Use of a cooling water intake structure includes obtaining cooling water by any sort of contract or arrangement with an independent supplier (or multiple suppliers) of cooling water if the supplier or suppliers withdraw(s) water from waters of the United States. Use of cooling water does not include obtaining cooling water from a public water system or the use of treated effluent that otherwise would be discharged to a water of the U.S. This provision is intended to prevent circumvention of these requirements by creating arrangements to receive cooling water from an entity that is not itself a point source.

(c) The threshold requirement that at least 25 percent of water withdrawn be used for cooling purposes must be measured on an average monthly basis. A new offshore oil and gas extraction facility meets the 25 percent cooling water threshold if, based on the new facility's design, any monthly average over a year for the percentage of cooling water withdrawn is expected to equal or exceed 25 percent of the total water withdrawn.

(d) Neither this subpart nor Subpart I applies to seafood processing vessels and offshore liquefied natural gas import terminals that are new facilities as defined in 40 CFR 125.83. Seafood processing vessels and offshore liquefied natural gas import terminals must meet requirements established by the Director on a case-by-case, best professional judgment (BPJ) basis.

§ 125.132 When must I comply with this subpart?

You must comply with this subpart when an NPDES permit containing requirements consistent with this subpart is issued to you.

§ 125.133 What special definitions apply to this subpart?

The following special definitions apply to this subpart:

Annual mean flow means the average of daily flows over a calendar year. Historical data (up to 10 years) must be used where available.

Cooling water means water used for contact or noncontact cooling, including water used for equipment cooling, evaporative cooling tower makeup, and dilution of effluent heat content. The intended use of the cooling water is to absorb waste heat rejected from the process or processes used, or from auxiliary operations on the facility's premises. Cooling water that is used in another industrial process either before or after it is used for cooling is considered process water for the purposes of calculating the percentage of a new offshore oil and gas extraction facility's intake flow that is used for cooling purposes in § 125.131(c).

Cooling water intake structure means the total physical structure and any associated constructed waterways used to withdraw cooling water from waters of the U.S. The cooling water intake structure extends from the point at which water is withdrawn from the surface water source up to, and including, the intake pumps.

Design intake flow means the value assigned (during the facility's design) to the total volume of water withdrawn from a source water body over a specific time period.

Design intake velocity means the value assigned (during the design of a cooling water intake structure) to the average speed at which intake water passes through the open area of the intake screen (or other device) against which organisms might be impinged or through which they might be entrained.

Entrainment means the incorporation of all life stages of fish and shellfish with intake water flow entering and passing through a cooling water intake structure and into a cooling water system.

Estuary means a semi-enclosed body of water that has a free connection with open seas and within which the seawater is measurably diluted with fresh water derived from land drainage. The salinity of an estuary exceeds 0.5 parts per thousand (by mass) but is typically less than 30 parts per thousand (by mass).

Fixed facility means a bottom founded offshore oil and gas extraction facility permanently attached to the seabed or subsoil of the outer continental shelf (*e.g.*, platforms, guyed towers, articulated gravity platforms) or a buoyant facility securely and substantially moored so that it cannot be moved without a special effort (*e.g.*, tension leg platforms, permanently moored semi-submersibles) and which is not intended to be moved during the production life of the well. This definition does not include mobile offshore drilling units (MODUs) (*e.g.*, drill ships, temporarily moored semi-submersibles, jack-ups, submersibles, tender-assisted rigs, and drill barges).

Hydraulic zone of influence means that portion of the source waterbody hydraulically affected by the cooling water intake structure withdrawal of water.

Impingement means the entrapment of all life stages of fish and shellfish on the outer part of an intake structure or against a screening device during periods of intake water withdrawal.

Maximize means to increase to the greatest amount, extent, or degree reasonably possible.

Minimize means to reduce to the smallest amount, extent, or degree reasonably possible.

Minimum ambient source water surface elevation means the mean low tidal water level for estuaries or oceans. The mean low tidal water level is the average height of the low water over at least 19 years.

New offshore oil and gas extraction facility means any building, structure, facility, or installation that:

(1) Meets the definition of a ''new source'' or ''new discharger'' in 40 CFR 122.2 and 122.29(b)(1) and (4);

(2) Is regulated by the Offshore and Coastal Subcategories of the Oil and Gas Extraction Point Source Category Effluent Guidelines in 40 CFR 435.10 or 40 CFR 435.40; and

(3) Commenced construction after [60 days from publication of the final rule].

Ocean means marine open coastal waters with a salinity greater than or equal to 30 parts per thousand (by mass).

Offshore liquefied natural gas (LNG) import terminal means any facility located in waters defined in 40 CFR 435.10 or 40 CFR 435.40 that liquefies, re-gasifies, transfers, or stores liquefied natural gas.

Sea chest means the underwater compartment or cavity within the facility or vessel hull or pontoon through which sea water is drawn in (for cooling and other purposes) or discharged.

Seafood processing vessel means any offshore or nearshore, floating, mobile, facility engaged in the processing of fresh, frozen, canned, smoked, salted or pickled seafood, seafood paste, mince, or meal.

Source water means the water body (waters of the U.S.) from which the cooling water is withdrawn.

Tidal excursion means the horizontal distance along the estuary or tidal river that a particle moves during one tidal cycle of ebb and flow.

Tidal river means the most seaward reach of a river or stream where the salinity is typically less than or equal to 0.5 parts per thousand (by mass) at a time of annual low flow and whose surface elevation responds to the effects of coastal lunar tides.

§ 125.134 As an owner or operator of a new offshore oil and gas extraction facility, what must I do to comply with this subpart?

(a)(1) The owner or operator of a new offshore oil and gas extraction facility must comply with:

(i) Track I in paragraph (b) or Track II in paragraph (c) of this section, if it is a fixed facility; or

(ii) Track I in paragraph (b) of this section, if it is *not* a fixed facility.

(2) In addition to meeting the requirements in paragraph (b) or (c) of this section, the owner or operator of a new offshore oil and gas extraction facility may be required to comply with paragraph (d) of this section.

(b) *Track I requirements for new offshore oil and gas extraction facilities.* (1)(i) New offshore oil and gas extraction facilities that withdraw greater than 2 MGD, *do not* employ sea chests as cooling water intake structures, and are fixed facilities must comply with all of the requirements in paragraphs (b)(2) through (8) of this section.

(ii) New offshore oil and gas extraction facilities that withdraw greater than 2 MGD, employ sea chests as cooling water intake structures, and are fixed facilities must comply with the requirements in paragraphs (b)(2), (3), (4), (6), (7), and (8) of this section.

(iii) New offshore oil and gas extraction facilities that withdraw greater than 2 MGD and are *not* fixed facilities must comply with the requirements in paragraphs (b)(2), (4), (6), (7), and (8) of this section.

(2) You must design and construct each cooling water intake structure at your facility to a maximum through-screen design intake velocity of 0.5 ft/s;

(3) For cooling water intake structures located in an estuary or tidal river, the total design intake flow over one tidal cycle of ebb and flow must be no greater than one (1) percent of the volume of the water column within the area centered about the opening of the intake with a diameter defined by the distance of one tidal excursion at the mean low water level;

(4) You must select and implement design and construction technologies or operational measures for minimizing impingement mortality of fish and shellfish if the Director determines that:

(i) There are threatened or endangered or otherwise protected federal, state, or tribal species, or critical habitat for these species, within the hydraulic zone of influence of the cooling water intake structure; or

(ii) Based on information submitted by any fishery management agency(ies) or other relevant information, there are migratory and/or sport or commercial species of impingement concern to the Director that pass through the hydraulic zone of influence of the cooling water intake structure; or

(iii) Based on information submitted by any fishery management agency(ies) or other relevant information, that the proposed facility, after meeting the technology-based performance requirements in paragraphs (b)(2) and (5) of this section, would still contribute unacceptable stress to the protected species, critical habitat of those species, or species of concern;

(5) You must select and implement design and construction technologies or operational measures for minimizing entrainment of entrainable life stages of fish and shellfish;

(6) You must submit the applicable application information required in 40 CFR 122.21(r) and § 125.136(b). If you are a fixed facility you must submit the information required in 40 CFR 122.21(r)(2) (except (r)(2)(iv)), (3), and (4) and § 125.136(b) of this subpart as part of your application. If you are a not a fixed facility, you must only submit the information required in 40 CFR 122.21(r)(2)(iv), (r)(3) (except r(3)(ii)) and § 125.136(b) as part of your application.

(7) You must implement the monitoring requirements specified in § 125.137;

(8) You must implement the recordkeeping requirements specified in § 125.138.

(c) *Track II requirements for new offshore oil and gas extraction facilities.* The owner or operator of a new offshore oil and gas extraction facility that is a fixed facility and chooses to comply under Track II must comply with the following requirements:

(1) You must demonstrate to the Director that the technologies employed will reduce the level of adverse environmental impact from your cooling water intake structures to a comparable level to that which you would achieve were you to implement the applicable requirements of paragraph (b)(2) and for fixed facilities without sea chests, paragraph (b)(5) of this section. This demonstration must include a showing that the impacts to fish and shellfish, including important forage and predator species will be comparable to those which would result if you were to implement the requirements of paragraph (b)(2) and for fixed facilities without sea chests, paragraph (b)(5) of this section. In identifying such species, the Director may consider information provided by any fishery management agency(ies) along with data and information from other sources.

(2) For cooling water intake structures located in an estuary or tidal river, the total design intake flow over one tidal cycle of ebb and flow must be no greater than one (1) percent of the volume of the water column within the area centered about the opening of the intake with a diameter defined by the distance of one tidal excursion at the mean low water level.

(3) You must submit the application information required in 40 CFR 122.21(r) and § 125.136(c).

(4) You must implement the monitoring requirements specified in § 125.137.

(5) You must implement the record-keeping requirements specified in § 125.138.

(d) You must comply with any more stringent requirements relating to the location, design, construction, and capacity of a cooling water intake structure or monitoring requirements at a new offshore oil and gas extraction facility that the Director deems are reasonably necessary to comply with any provision of Federal or State law, including compliance with applicable state water quality standards (including designated uses, criteria, and antidegradation requirements).

§ 125.135 May alternative requirements be authorized?

(a) Any interested person may request that alternative requirements less stringent than those specified in § 125.134(a) through (d) be imposed in the permit. The Director may establish alternative requirements less stringent than the requirements of § 125.134(a) through (d) only if:

(1) There is an applicable requirement under § 125.134(a) through (d);

(2) The Director determines that data specific to the facility indicate that compliance with the requirement at issue would result in compliance costs wholly out of proportion to the costs EPA considered in establishing the requirement at issue or would result in significant adverse impacts on local water resources other than impingement or entrainment, or significant adverse impacts on energy markets;

(3) The alternative requirement requested is no less stringent than justified by the wholly out of proportion cost or the significant adverse impacts on local water resources other than impingement or entrainment, or significant adverse impacts on energy markets; and

(4) The alternative requirement will ensure compliance with other applicable provisions of the Clean Water Act and any applicable requirement of Federal or State law.

(b) The burden is on the person requesting the alternative requirement to demonstrate that alternative requirements should be authorized.

§ 125.136 As an owner or operator of a new offshore oil and gas extraction facility, what must I collect and submit when I apply for my new or reissued NPDES permit?

(a)(1) As an owner or operator of a new offshore oil and gas extraction facility, you must submit to the Director a statement that you intend to comply with either:

(i) The Track I requirements for new offshore oil and gas extraction facilities in § 125.134(b); or

(ii) If you are a fixed facility, the Track II requirements in § 125.134(c).

(2) You must also submit the application information required by 40 CFR 122.21(r) and the information required in either paragraph (b) of this section for Track I or, if you are a fixed facility that chooses to comply under Track II, paragraph (c) of this section for Track II when you apply for a new or reissued NPDES permit in accordance with 40 CFR 122.21.

(b) *Track I application requirements.* To demonstrate compliance with Track I requirements in § 125.134(b), you must collect and submit to the Director the information in paragraphs (b)(1) through (3) of this section.

(1) *Velocity information.* You must submit the following information to the Director to demonstrate that you are complying with the requirement to meet a maximum through-screen design intake velocity of no more than 0.5 ft/s at each cooling water intake structure as required in § 125.134(b)(2):

(i) A narrative description of the design, structure, equipment, and operation used to meet the velocity requirement; and

(ii) Design calculations showing that the velocity requirement will be met at minimum ambient source water surface elevations (based on best professional judgment using available hydrological data) and maximum head loss across the screens or other device.

(2) *Source waterbody flow information.* If you are a fixed facility and your cooling water intake structure is located in an estuary or tidal river, you must provide the mean low water tidal excursion distance and any supporting documentation and engineering calculations to show that your cooling water intake structure facility meets the flow requirements in § 125.134(b)(3).

(3) *Design and Construction Technology Plan.* To comply with § 125.134(b)(4) and/or (5), if applicable, you must submit to the Director the following information in a Design and Construction Technology Plan:

(i) If the Director determines that additional impingement requirements should be included in your permit:

(A) Information to demonstrate whether or not you meet the criteria in § 125.134(b)(4);

(B) Delineation of the hydraulic zone of influence for your cooling water intake structure;

(ii) New offshore oil and gas extraction facilities required to install design and construction technologies and/or operational measures must develop a plan explaining the technologies and measures you have selected. (Examples of appropriate technologies include, but are not limited to, increased opening to cooling water intake structure to decrease design intake velocity, wedgewire screens, fixed screens, velocity caps, location of cooling water intake opening in waterbody, *etc.* Examples of appropriate operational measures include, but are not limited to, seasonal shutdowns or reductions in flow, continuous operations of screens, *etc.*) The plan must contain the following information, if applicable:

(A) A narrative description of the design and operation of the design and construction technologies, including fish-handling and return systems, that you will use to maximize the survival of those species expected to be most susceptible to impingement. Provide species-specific information that demonstrates the efficacy of the technology;

(B) To demonstrate compliance with 125.134(b)(5), if applicable, a narrative description of the design and operation of the design and construction technologies that you will use to minimize entrainment of those species expected to be the most susceptible to entrainment. Provide species-specific information that demonstrates the efficacy of the technology; and

(C) Design calculations, drawings, and estimates to support the descriptions provided in paragraphs (b)(3)(iii)(A) and (B) of this section.

(c) *Application requirements for Track II.* If you are a fixed facility and have chosen to comply with the requirements of Track II in § 125.134(c) you must collect and submit the following information:

(1) *Source waterbody flow information.* If your cooling water intake structure is located in an estuary or tidal river, you must provide the mean low water tidal excursion distance and any supporting documentation and engineering calculations to show that your cooling water intake structure facility meets the flow requirements in § 125.134(c)(2);

(2) *Track II Comprehensive Demonstration Study.* You must perform and submit the results of a Comprehensive Demonstration Study (Study). This information is required to characterize the source water baseline in the vicinity of the cooling water intake structure(s), characterize operation of the cooling water intake(s), and to confirm that the technology(ies) proposed and/or implemented at your cooling water intake structure reduce the impacts to fish and shellfish to levels comparable to those you would achieve were you to implement the applicable requirements in § 125.134(b)

(i) To meet the ''comparable level'' requirement, you must demonstrate that:

(A) You have reduced impingement mortality of all life stages of fish and shellfish to 90 percent or greater of the reduction that would be achieved through the applicable requirements in § 125.134(b)(2); and

(B) If you are a facility without sea chests, you have minimized entrainment of entrainable life stages of fish and shellfish in accordance with § 125.134(b)(5);

(ii) You must develop and submit a plan to the Director containing a proposal for how information will be collected to support the study. The plan must include:

(A) A description of the proposed and/or implemented technology(ies) to be evaluated in the Study;

(B) A list and description of any historical studies characterizing the physical and biological conditions in the vicinity of the proposed or actual intakes and their relevancy to the proposed Study. If you propose to rely on existing source water body data, it must be no more than 5 years old, you must demonstrate that the existing data are sufficient to develop a scientifically valid estimate of potential impingement mortality and (if applicable) entrainment impacts, and provide documentation showing that the data were collected using appropriate quality assurance/quality control procedures;

(C) Any public participation or consultation with Federal or State agencies undertaken in developing the plan; and

(D) A sampling plan for data that will be collected using actual field studies in the source water body. The sampling plan must document all methods and quality assurance procedures for sampling, and data analysis. The sampling and data analysis methods you propose must be appropriate for a quantitative survey and based on consideration of methods used in other studies performed in the source water body. The sampling plan must include a description of the study area (including the area of influence of the cooling water intake structure and at least 100 meters beyond); taxonomic identification of the sampled or evaluated biological assemblages (including all life stages of fish and shellfish); and sampling and data analysis methods; and

(iii) You must submit documentation of the results of the Study to the Director. Documentation of the results of the Study must include:

(A) *Source Water Biological Study.* The Source Water Biological Study must include:

(*1*) A taxonomic identification and characterization of aquatic biological resources including: a summary of historical and contemporary aquatic biological resources; determination and description of the target populations of concern (those species of fish and shellfish and all life stages that are most susceptible to impingement and entrainment); and a description of the abundance and temporal/spatial characterization of the target populations based on the collection of multiple years of data to capture the seasonal and daily activities (*e.g.*, spawning, feeding and water column migration) of all life stages of fish and shellfish found in the vicinity of the cooling water intake structure;

(*2*) An identification of all threatened or endangered species that might be susceptible to impingement and entrainment by the proposed cooling water intake structure(s); and

(*3*) A description of additional chemical, water quality, and other anthropogenic stresses on the source waterbody.

(B) *Evaluation of potential cooling water intake structure effects.* This evaluation will include:

(*1*) Calculations of the reduction in impingement mortality and, if applicable, entrainment of all life stages

of fish and shellfish that would need to be achieved by the technologies you have selected to implement to meet requirements under Track II. To do this, you must determine the reduction in impingement mortality and entrainment that would be achieved by implementing the requirements of § 125.134(b)(2) and, for facilities without sea chests, § 125.134(b)(5) of Track I at your site.

(*2*) An engineering estimate of efficacy for the proposed and/or implemented technologies used to minimize impingement mortality and (if applicable) entrainment of all life stages of fish and shellfish and maximize survival of impinged life stages of fish and shellfish. You must demonstrate that the technologies reduce impingement mortality and (if applicable) entrainment of all life stages of fish and shellfish to a comparable level to that which you would achieve were you to implement the requirements in § 125.134(b)(2) and, for facilities without sea chests, § 125.134(b)(5) of Track I. The efficacy projection must include a site-specific evaluation of technology(ies) suitability for reducing impingement mortality and (if applicable) entrainment based on the results of the Source Water Biological Study in paragraph (c)(2)(iv)(A) of this section. Efficacy estimates may be determined based on case studies that have been conducted in the vicinity of the cooling water intake structure and/or site-specific technology prototype studies.

(C) *Verification monitoring plan.* You must include in the Study a plan to conduct, at a minimum, two years of monitoring to verify the full-scale performance of the proposed or implemented technologies, operational measures. The verification study must begin at the start of operations of the cooling water intake structure and continue for a sufficient period of time to demonstrate that the facility is reducing the level of impingement mortality and (if applicable) entrainment to the level documented in paragraph (c)(2)(iii)(B) of this section. The plan must describe the frequency of monitoring and the parameters to be monitored. The Director will use the verification monitoring to confirm that you are meeting the level of impingement mortality and entrainment reduction required in § 125.134(c), and that the operation of the technology has been optimized.

§ 125.137 As an owner or operator of a new offshore oil and gas extraction facility, must I perform monitoring?

As an owner or operator of a new offshore oil and gas extraction facility, you will be required to perform monitoring to demonstrate your compliance with the requirements specified in § 125.134 or alternative requirements under § 125.135.

(a) *Biological monitoring.* (1)(i) Fixed facilities without sea chests that choose to comply with the Track I requirements in § 125.134(b)(1)(i) must monitor for entrainment. These facilities are not required to monitor for impingement, unless the Director determines that the information would be necessary to evaluate the need for or compliance with additional requirements in accordance with § 125.134(b)(4) or more stringent requirements in accordance with § 125.134(d).

(ii) Fixed facilities with sea chests that choose to comply with Track I requirements are not required to perform biological monitoring unless the Director determines that the information would be necessary to evaluate the need for or compliance with additional requirements in accordance with § 125.134(b)(4) or more stringent requirements in accordance with § 125.134(d).

(iii) Facilities that are not fixed facilities are not required to perform biological monitoring unless the Director determines that the information would be necessary to evaluate the need for or compliance with additional requirements in accordance with § 125.134(b)(4) or more stringent requirements in accordance with § 125.134(d).

(iv) Fixed facilities with sea chests that choose to comply with Track II requirements in accordance with § 125.134(c), must monitor for impingement only. Fixed facilities without sea chests, must monitor for both impingement and entrainment.

(2) Monitoring must characterize the impingement rates and (if applicable) entrainment rates of commercial, recreational, and forage base fish and shellfish species identified in the Source Water Baseline Biological Characterization data required by 40 CFR 122.21(r)(4), identified in the Comprehensive Demonstration Study required by § 125.136(c)(2), or as specified by the Director.

(3) The monitoring methods used must be consistent with those used for the Source Water Baseline Biological Characterization data required in 40 CFR 122.21(r)(4), those used by the Comprehensive Demonstration Study required by § 125.136(c)(2), or as specified by the Director. You must follow the monitoring frequencies identified below for at least two (2) years after the initial permit issuance. After that time, the Director may approve a request for less frequent sampling in the remaining years of the permit term and when the permit is reissued, if supporting data show that less frequent monitoring would still allow for the detection of any seasonal and daily variations in the species and numbers of individuals that are impinged or entrained.

(4) *Impingement sampling.* You must collect samples to monitor impingement rates (simple enumeration) for each species over a 24-hour period and no less than once per month when the cooling water intake structure is in operation.

(5) *Entrainment sampling.* If your facility is subject to the requirements of § 125.134(b)(1)(i) or (c), you must collect samples to monitor entrainment rates (simple enumeration) for each species over a 24-hour period and no less than biweekly during the primary period of reproduction, larval recruitment, and peak abundance identified during the Source Water Baseline Biological Characterization required by 40 CFR 122.21(r)(4) or the Comprehensive Demonstration Study required in § 125.136(c)(2). You must collect samples only when the cooling water intake structure is in operation.

(b) *Velocity monitoring.* If your facility uses a surface intake screen systems, you must monitor head loss across the screens and correlate the measured value with the design intake velocity. The head loss across the intake screen must be measured at the minimum ambient source water surface elevation (best professional judgment based on available hydrological data). The maximum head loss across the screen for each cooling water intake structure must be used to determine compliance with the velocity requirement in § 125.134(b)(2). If your facility uses devices other than surface intake screens, you must monitor velocity at the point of entry through the device. You must monitor head loss or velocity during initial facility startup, and thereafter, at the frequency specified in your NPDES permit, but no less than once per quarter.

(c) *Visual or remote inspections.* You must either conduct visual inspections or employ remote monitoring devices during the period the cooling water intake structure is in operation. You must conduct visual inspections at least weekly to ensure that any design and construction technologies required in § 125.134(b)(4), (b)(5), (c), and/or (d) are

maintained and operated to ensure that they will continue to function as designed. Alternatively, you must inspect via remote monitoring devices to ensure that the impingement and entrainment technologies are functioning as designed.

§ 125.138 As an owner or operator of a new offshore oil and gas extraction facility, must I keep records and report?

As an owner or operator of a new offshore oil and gas extraction facility you are required to keep records and report information and data to the Director as follows:

(a) You must keep records of all the data used to complete the permit application and show compliance with the requirements, any supplemental information developed under § 125.136, and any compliance monitoring data submitted under § 125.137, for a period of at least three (3) years from the date of permit issuance. The Director may require that these records be kept for a longer period.

(b) You must provide the following to the Director in a yearly status report:

(1) For fixed facilities, biological monitoring records for each cooling water intake structure as required by § 125.137(a);

(2) Velocity and head loss monitoring records for each cooling water intake structure as required by § 125.137(b); and

(3) Records of visual or remote inspections as required in § 125.137(c).

§ 125.139 As the Director, what must I do to comply with the requirements of this subpart?

(a) *Permit application.* As the Director, you must review materials submitted by the applicant under 40 CFR 122.21(r), § 125.135, and § 125.136 at the time of the initial permit application and before each permit renewal or reissuance.

(1) After receiving the initial permit application from the owner or operator of a new offshore oil and gas extraction facility, the Director must determine applicable standards in § 125.134 or § 125.135 to apply to the new offshore oil and gas extraction facility. In addition, the Director must review materials to determine compliance with the applicable standards.

(2) For each subsequent permit renewal, the Director must review the application materials and monitoring data to determine whether requirements, or additional requirements, for design and construction technologies or operational measures should be included in the permit.

(3) For Track II facilities, the Director may review the information collection proposal plan required by § 125.136(c)(2)(ii). The facility may initiate sampling and data collection activities prior to receiving comment from the Director.

(b) *Permitting requirements.* Section 316(b) requirements are implemented for a facility through an NPDES permit. As the Director, you must determine, based on the information submitted by the new offshore oil and gas extraction facility in its permit application, the appropriate requirements and conditions to include in the permit based on the track (Track I or Track II), or alternative requirements in accordance with § 125.135, the new offshore oil and gas extraction facility has chosen to comply with. The following requirements must be included in each permit:

(1) *Cooling water intake structure requirements.* At a minimum, the permit conditions must include the performance standards that implement the applicable requirements of § 125.134(b)(2), (3), (4) and (5); § 125.134(c)(1) and (2); or § 125.135.

(i) For a facility that chooses Track I, you must review the Design and Construction Technology Plan required in § 125.136(b)(3) to evaluate the suitability and feasibility of the technology proposed to minimize impingement mortality and (if applicable) entrainment of all life stages of fish and shellfish. In the first permit issued, you must include a condition requiring the facility to reduce impingement mortality and/or entrainment commensurate with the implementation of the technologies in the permit. Under subsequent permits, the Director must review the performance of the technologies implemented and require additional or different design and construction technologies, if needed to minimize impingement mortality and/or entrainment of all life stages of fish and shellfish. In addition, you must consider whether more stringent conditions are reasonably necessary in accordance with § 125.134(d).

(ii) For a fixed facility that chooses Track II, you must review the information submitted with the Comprehensive Demonstration Study information required in § 125.136(c)(2), evaluate the suitability of the proposed design and construction technology and/or operational measures to determine whether they will reduce both impingement mortality and/or entrainment of all life stages of fish and shellfish to 90 percent or greater of the reduction that could be achieved through Track I. In addition, you must review the Verification Monitoring Plan in § 125.136(c)(2)(iii)(C) and require that the proposed monitoring begin at the start of operations of the cooling water intake structure and continue for a sufficient period of time to demonstrate that the technologies and operational measures meet the requirements in § 125.134(c)(1). Under subsequent permits, the Director must review the performance of the additional and/or different technologies or measures used and determine that they reduce the level of adverse environmental impact from the cooling water intake structures to a comparable level that the facility would achieve were it to implement the requirements of § 125.134(b)(2) and, if applicable, § 125.134(b)(5).

(iii) If a facility requests alternative requirements in accordance with § 125.135, you must determine if data specific to the facility meet the requirements in § 125.135(a) and include in the permit requirements that are no less stringent than justified by the wholly out of proportion cost or the significant adverse impacts on local water resources other than impingement or entrainment, or significant adverse impacts on energy markets.

(2) *Monitoring conditions.* At a minimum, the permit must require the permittee to perform the monitoring required in § 125.137. You may modify the monitoring program when the permit is reissued and during the term of the permit based on changes in physical or biological conditions in the vicinity of the cooling water intake structure. The Director may require continued monitoring based on the results of the Verification Monitoring Plan in § 125.136(c)(2)(iii)(C).

(3) *Record keeping and reporting.* At a minimum, the permit must require the permittee to report and keep records as required by § 125.138.

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the California tiger salamander (*Ambystoma californiense*) in Santa Barbara County; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AT44

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the California tiger salamander (*Ambystoma californiense*) in Santa Barbara County

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), designate critical habitat for the Santa Barbara County population of California tiger salamander (*Ambystoma californiense*) (referred to here as California tiger salamander or CTS in Santa Barbara County) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 11,180 acres (ac) (4,523 hectares (ha)) fall within the boundaries of the critical habitat designation. The critical habitat is located in northern Santa Barbara County, California. Collectively, we excluded a total of 2,740 ac (1,109 ha) of privately-owned lands from this final critical habitat designation.

DATES: This final rule is effective December 27, 2004.

ADDRESSES: Comments and materials received, as well as supporting documentation used in the preparation of this final rule, will be available for public inspection, by appointment, during normal business hours at the Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.

FOR FURTHER INFORMATION CONTACT: Diane Noda, Field Supervisor, Ventura Fish and Wildlife Office (*see* **ADDRESSES** section) (telephone 805/644–1766; facsimile 805/644–3958).

SUPPLEMENTARY INFORMATION:

Designation of Critical Habitat Provides Little Additional Protection to Species

In 30 years of implementing the Act, the Service has found that the designation of statutory critical habitat provides little additional protection to most listed species, while consuming significant amounts of available conservation resources. The Service's present system for designating critical habitat has evolved since its original statutory prescription into a process that provides little real conservation benefit, is driven by litigation and the courts rather than biology, limits our ability to fully evaluate the science involved, consumes enormous agency resources, and imposes huge social and economic costs. The Service believes that additional agency discretion would allow our focus to return to those actions that provide the greatest benefit to the species most in need of protection.

Role of Critical Habitat in Actual Practice of Administering and Implementing the Act

While attention to and protection of habitat is paramount to successful conservation actions, we have consistently found that, in most circumstances, the designation of critical habitat is of little additional value for most listed species, yet it consumes large amounts of conservation resources. Sidle (1987) stated, ''Because the Act can protect species with and without critical habitat designation, critical habitat designation may be redundant to the other consultation requirements of section 7.'' Currently, only 445 species or 36 percent of the 1,244 listed species in the U.S. under the jurisdiction of the Service have designated critical habitat. We address the habitat needs of all 1,244 listed species through conservation mechanisms such as listing, section 7 consultations, the Section 4 recovery planning process, the Section 9 protective prohibitions of unauthorized take, Section 6 funding to the States, and the Section 10 incidental take permit process. The Service believes that it is these measures that may make the difference between extinction and survival for many species.

We note, however, that a recent 9th Circuit judicial opinion, *Gifford Pinchot Task Force* v. *United States Fish and Wildlife Service,* has invalidated the Service's regulation defining destruction or adverse modification of critical habitat. We are currently reviewing the decision to determine what effect it may have on the outcome of consultations pursuant to Section 7 of the Act.

Procedural and Resource Difficulties in Designating Critical Habitat

We have been inundated with lawsuits for our failure to designate critical habitat, and we face a growing number of lawsuits challenging critical habitat determinations once they are made. These lawsuits have subjected the Service to an ever-increasing series of court orders and court-approved settlement agreements, compliance with which now consumes nearly the entire listing program budget. This leaves the Service with little ability to prioritize its activities to direct scarce listing resources to the listing program actions with the most biologically urgent species conservation needs.

The consequence of the critical habitat litigation activity is that limited listing funds are used to defend active lawsuits, to respond to Notices of Intent (NOIs) to sue relative to critical habitat, and to comply with the growing number of adverse court orders. As a result, listing petition responses, the Service's own proposals to list critically imperiled species, and final listing determinations on existing proposals are all significantly delayed.

The accelerated schedules of court ordered designations have left the Service with almost no ability to provide for adequate public participation or to ensure a defect-free rulemaking process before making decisions on listing and critical habitat proposals due to the risks associated with noncompliance with judicially-imposed deadlines. This in turn fosters a second round of litigation in which those who fear adverse impacts from critical habitat designations challenge those designations. The cycle of litigation appears endless, is very expensive, and in the final analysis provides relatively little additional protection to listed species.

The costs resulting from the designation include legal costs, the cost of preparation and publication of the designation, the analysis of the economic effects and the cost of requesting and responding to public comment, and in some cases the costs of compliance with the National Environmental Policy Act (NEPA). None of these costs result in any benefit to the species that is not already afforded by the protections of the Act enumerated earlier, and they directly reduce the funds available for direct and tangible conservation actions.

Background

For background information, please see the proposed designation of critical habitat for the Santa Barbara County Distinct Vertebrate Population Segment (DPS) of the California tiger salamander published on January 22, 2004 (69 FR 3064). That information is incorporated by reference into this final rule.

Previous Federal Action

On February 25, 2003, the Environmental Defense Center and Center for Biological Diversity filed a complaint challenging our failure to designate critical habitat for the Santa Barbara County DPS of the California tiger salamander (*Environmental Defense Center et al.* v. *U.S. Fish and Wildlife Service et al.,* EVCD 03–00195

(C.D. Cal)). By an order dated August 7, 2003, the district court ordered us to publish a proposed rule to designate critical habitat for the Santa Barbara County DPS of the California tiger salamander by January 15, 2004, and a final rule by November 15, 2004. We published the proposed rule on January 22, 2004 (69 FR 3064).

On August 4, 2004, we made a new determination regarding the listing status of the California tiger salamander. This determination changed the status of the Santa Barbara population. We determined that the California tiger salamander is threatened rangewide, and we published this finding along with a Special Rule exempting existing routine ranching practices throughout the species' range (69 FR 47212). New version: The rule included a detailed analysis of threats to the California tiger salamander, Central population, and a reclassification of the Santa Barbara County and Sonoma County populations. As a result, we removed these populations as separately listed DPSs, and listed the entire California tiger salamander species as threatened.

We are issuing this final designation of critical habitat for the California tiger salamander in the Santa Barbara County portion of its range in compliance with the court's order (described above), noting that it does not include all portions of the range of the entity now listed. We anticipate completing the critical habitat designation for California tiger salamander rangewide through future rulemaking. We proposed critical habitat for the California tiger salamander, Central population, on August 10, 2004 (69 FR 48570).

Summary of Comments and Recommendations

We contacted appropriate Federal, State, and local agencies, scientific organizations, and other interested parties and invited them to comment on the proposed critical habitat designation for the CTS in Santa Barbara County. In addition, we invited public comment through the publication of a notice in the Santa Barbara News-Press on January 26, 2004, and the Santa Maria Times on January 28, 2004.

In the January 22, 2004, proposed critical habitat designation (69 FR 3064), we requested that all interested parties submit comments on the specifics of the proposal, including information related to the critical habitat designation, unit boundaries, species occurrence information and distribution, land use designations that may affect critical habitat, potential economic effects of the proposed designation, benefits associated with the critical habitat designation, potential exclusions and the associated rationale for the exclusions, and methods used to designate critical habitat. We also contacted all appropriate Federal, State, and local agencies, scientific organizations, and other interested parties and invited them to comment. This was accomplished through letters and news releases mailed to affected elected officials, media outlets, local jurisdictions, interest groups and other interested individuals. In addition, we invited public comment through the publication of legal notices in newspapers throughout Santa Barbara County.

We received several requests for a public hearing and an extension of the comment period. We announced the reopening of the comment period and the date and time of the public hearing on April 13, 2004 (69 FR 19364), and invited additional comments in letters to appropriate elected officials; Federal, State, and local agencies; scientific organizations; and other interested parties. We also published notices in several news sources, including the **Federal Register**, Santa Barbara News-Press, and the Santa Maria Times. We held a public hearing in Santa Maria, California, on May 11, 2004. Thirty-two individuals gave testimony on the proposed critical habitat designation for the CTS in Santa Barbara County.

We provided notification of availability of the draft economic analysis (DEA) through letters and news releases faxed and/or mailed to affected elected officials, media outlets, local jurisdictions, and interest groups. We also published a notice of its availability in the **Federal Register** on October 7, 2004 (69 FR 60138) and made the DEA and associated material available on our Ventura Fish and Wildlife Office Internet site. The reopened comment period closed on November 8, 2004.

We received a cumulative total of 71 comment letters and electronic mail messages (e-mails) during all of the comment periods. We reviewed all comments received for substantive issues and new information regarding the CTS in Santa Barbara County. We grouped the comments into three categories: peer review comments, State comments, or public comments. We grouped similar public comments into six general issue categories relating specifically to the proposed critical habitat determination and/or the DEA. Substantive comments and accompanying information have either been incorporated directly into the final rule, economic analysis documents, and/or they have been addressed in the following summary.

Peer Review

In accordance with our joint policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we solicited review from at least three appropriate and independent specialists/experts regarding the proposed rule. The purpose of such review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses.

We solicited peer review from 11 individuals who have detailed knowledge of and expertise in amphibian biology in general, or salamander biology specifically, as well in scientific principles and conservation biology. The individuals were asked to review and comment on the specific assumptions and conclusions regarding the proposed designation of critical habitat. Three of the eleven reviewers submitted comments on the proposed designation. The three reviewers strongly endorsed the approach we used in our proposal that emphasized the importance of conserving aquatic habitat in the context of surrounding upland habitat. The reviewers felt that this approach is crucial for the conservation and long-term survival of the CTS in Santa Barbara County. They also stated that the rule placed appropriate emphasis on protecting the remaining habitat. All generally supported our methodology and conclusions.

Comment (1) (Peer): One peer reviewer cited the importance of conserving the historical connectivity between the six critical habitat units and suggested that all lands surrounding and between Units 3 (Western Alamos/Careaga), 4 (Eastern Los Alamos), 5 (Purisima Hills), and 6 (Santa Rita Valley) be included as critical habitat. The reviewer also suggested that additional historical locations of the CTS in Santa Barbara County be considered for critical habitat, and specifically recommended inclusion of the known pond near Unit 6 (Santa Rita Valley) and some upland habitat surrounding Unit 2 (Eastern Santa Maria).

Our Response: Although we agree that preserving connectivity between known breeding ponds is essential for the conservation of the CTS in Santa Barbara County, we do not believe that unoccupied and historical locations are essential for the conservation of the species. The science subteam of the recovery team for CTS in Santa Barbara County determined that the CTS in Santa Barbara County could be conserved by protecting habitat in six disparate conservation areas, excluding

unoccupied and/or historical locations between these six conservation areas. These six conservation areas were identified over a series of meetings that took place between 2002 and 2003 (Service files 2002–2003). These six conservation areas closely resemble the critical habitat units contained in this rule. The six units that we have designated as critical habitat provide for the essential life-cycle needs of the species, and provide the habitat components essential for the conservation of this species (*i.e.*, the primary constituent elements (PCEs) described below in the Primary Constituent Elements section).

State Agencies

We received comments from the California Department of Transportation (Caltrans). Technical data provided by Caltrans has been incorporated into, or addressed in, this final rule, while other issues raised by Caltrans are addressed below.

Comment (2) (State): Caltrans commented that it is unclear why Unit 1 (Western Santa Maria/Orcutt) extends to the western side of State Highway 1, from Black Road to Clark Road. Caltrans requested that this boundary be along the eastern State Highway right-of-way (ROW). Caltrans stated that the rule is written so that it is difficult to discern whether the State ROW is included in the boundary. Caltrans commented that, as currently written in the proposed rule, the State Highway appears to be the boundary. Caltrans stated that the boundary should be relocated outside the State ROW and clearly defined. Caltrans indicated that State ROWs are regularly disturbed and do not provide essential habitat for California tiger salamanders. Futhermore, Caltrans stated that including State ROWs is not necessary and would be prohibitive in terms of both staff time and unnecessary expenses to the State, and would provide little to no benefit to sensitive species.

Our Response: ROWs are not included in this designation.

Comment (3) (State): Caltrans stated that the maps provided in the **Federal Register** need to be more informative with a greater level of detail that accurately defines the boundaries of proposed critical habitat units. Caltrans suggested that the Service publish Geographic Information System (GIS) maps.

Our Response: The maps in the **Federal Register** are meant to provide the general location and shape of critical habitat. The proposed rule also included Universal Transverse Mercator (UTM) coordinates of the proposed critical habitat units. These legal descriptions are readily plotted and transferable to a variety of mapping formats, and are available electronically upon request for use with GIS programs. The scale of the legal descriptions is sufficiently detailed for locating the extent and configuration of the units.

In addition, at the public hearing, the maps were expanded to wall size to assist the public in better understanding the proposal. These larger scale maps were also provided to individuals upon request. Furthermore, we provided direct assistance in response to written or telephone questions with regard to mapping and land ownership within the proposed designation.

Comment (4) (State): Caltrans stated that clarification is needed where the rule reads ''Federal agencies already consult'' on activities that include ''road construction and maintenance, right-of-way designation, and regulation funded or permitted by the Federal Highway Administration (FHWA).'' Caltrans suggested that this be changed to read ''The FHWA funds new construction and does not fund the routine operations and maintenance of the State highway system.''

Our Response: We have changed the language in the preamble to this final rule to reflect this clarification.

Other Public Comments and Responses

We address other substantive comments and accompanying information in the following summary. Relatively minor editing changes and reference updates suggested by commenters have been incorporated into this final rule or the economic analysis documents, as appropriate.

Issue 1—Habitat and Species Specific Information

Comment (5): One commenter stated that historical populations of the salamander are unknown and could, in fact, be increasing. One commenter stated that many pictographs that exist in the traditional tribal domain of the Chumash (from Monterey to Malibu) display the California tiger salamander. The commenter concluded that this points to an amphibian that was very common among the Chumash culture and located over a wide area. Several commenters stated that not enough has been done to demonstrate that this amphibian is threatened.

Our Response: The historical distribution and numbers of CTS in Santa Barbara County are not known. The CTS in Santa Barbara County is presently found in 6 disparate locations in northern Santa Barbara County. Because this species spends much of its life underground, only a portion of the total number of animals migrate to pools to breed each year and animals do not always breed in their natal pool or pond, estimates of the total number of CTS in Santa Barbara County are difficult to make. This difficulty has been noted by a number of biologists (Jennings and Hayes 1994; Shaffer *et al.* 1993).

When making a listing determination, we carefully consider the best available scientific and commercial data regarding the historic and current ranges of the taxon under consideration, as well as the abundance of the species (if known), and the pattern, imminence, and magnitude of threats relative to the species' distribution. After completing such an analysis for the CTS in Santa Barbara County in 2000, we listed the Santa Barbara County animals as an endangered DPS. Recently, we re-evaluated that determination in the context of California tiger salamanders rangewide. We determined that the best available evidence supports a threatened listing for a single species rangewide. The original analysis and our more recent analysis are available in our final rules that published in the **Federal Register** on (September 21, 2000, 65 FR 57242) and (August 4, 2004, 69 FR 47212).

Comment (6): One commenter stated that there is no scientific proof that protecting habitat will protect a species from anything. Another commenter stated that critical habitat does not further the conservation efforts for protecting the California tiger salamander.

Our Response: The fundamental importance of habitat to wildlife populations was established long ago (*e.g.*, Grinnell 1917, 1928, as cited in Real and Levin 1991; Leopold 1933; Noss *et al.* 1997). ''[All] organisms require appropriate habitats if they are to survive'' (Ehrlich 1988, p. 22). Therefore, we conclude that the protection of habitat is an important conservation action. Habitat provides species with cover, shelter, protection from the elements and predation, and space to breed and raise offspring.

In the case of the California tiger salamander, aquatic habitat is needed for breeding, and upland habitat is needed for foraging, sheltering, and protection from predation and the elements (such as the hot, dry weather typical of Santa Barbara County during the non-breeding season). In addition, upland habitat located between aquatic habitats is essential in maintaining gene flow and for recolonization of sites that are temporarily extirpated.

The designation of critical habitat can play a role in conserving the California tiger salamander. Designation ensures that federal agency actions affecting essential California tiger salamander habitat are carefully reviewed so that the habitat will remain functional to serve its intended conservation role.

Comment (7): One commenter stated that the area designated for critical habitat is not threatened.

Our Response: The known locations of CTS in Santa Barbara County fall into six disparate areas of Santa Barbara County. Habitat in these areas is threatened with loss and/or fragmentation (*i.e.*, reduction in habitat quantity). We are also aware of several factors that may reduce habitat quality within these areas; the presence of introduced species which compete with or feed on California tiger salamanders; unsuitable grazing (see August 4, 2004, Special Rule in 69 FR at 47241), and disturbance from past oil production cleanup efforts. Each of the six areas has a distinctive combination of habitat types, breeding pond types, landscape features, surrounding land uses, and topography. Because of the existing population level, and the types of threats to these populations, we determined that these six areas were essential to the conservation of the species.

Comment (8): One commenter stated that the Service should find critical habitat for the salamander to be not warranted. The commenter stated that the designation would provide a second layer of protection but the listing itself provides all that is required to protect the species.

Our Response: The term, ''not warranted,'' applies to petition findings and is a result that is possible for a petition finding. We do not have a not warranted option for a critical habitat designation. We can find that critical habitat is not prudent but the courts have found that the not prudent exception is narrow and should be sparsely applied.

The designation means that Federal agencies are required to consult with the Service on the impacts of actions they undertake, fund, or permit on designated critical habitat. While in many cases, these requirements may not provide substantial additional protection for most species, they do direct the Service to consider specifically whether a proposed action will affect the functionality of essential habitat to serve its intended conservation role for a species rather than to focus exclusively on whether the action is likely to jeopardize the species' continued existence. We agree, however, that even absent a critical habitat designation, Federal agencies are still required to consult on the impacts of their activities on listed species and their habitat.

Comment (9): One commenter stated that the determination on page 3073 of the proposed designation (January 22, 2004, 69 FR 3064) under Summary is not substantiated.

Our Response: On page 3073 of the proposed rule, it reads ''In summary, we propose six areas where populations of California tiger salamander are known to occur as critical habitat because we believe protection of those areas is essential to the conservation of the species.'' As required under section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, we identified those areas containing the physical and biological features (PCEs) that are essential to the conservation of the CTS in Santa Barbara County and their need for special management considerations or protections using the best scientific data available. Two of the three peer reviewers agree that the areas we are designating as critical habitat provide for the essential life-cycle needs of the CTS in Santa Barbara County and provide the habitat components essential for the conservation (PCEs) of this species. The third reviewer believes that the area included in the critical habitat designation should be expanded to include some unoccupied areas.

Comment (10): One commenter stated that the Service failed to mention that most of Unit 2 has historically been cultivated.

Our Response: The fact that an area has been cultivated historically does not necessarily make it unsuitable for California tiger salamanders. However, the trend in Santa Barbara County has been to move from dry farming and grazing to more intensive forms of agriculture such as row-cropping and vineyards. This trend resulted in the rapid loss of California tiger salamander upland habitat which was the primary threat to the species at the time of listing in 2000 (September 21, 2000, 65 FR 57242). Although we are aware that most of Unit 2 (Eastern Santa Maria) has historically been cultivated, portions of Unit 2 are fallow and provide upland habitat for the CTS in Santa Barbara County. In addition, some cultivated lands in Unit 2 function as important connectivity habitat between ponds.

Issue 2—Costs and Regulatory Burden

Comment (11): One commenter stated that the designation is an unneeded cost to the taxpayer and that much of the habitat features that make up this designation are already listed for other species within the area.

Our Response: Section 4 of the Endangered Species Act of 1973, as amended, and our implementing regulations, state that critical habitat shall be designated for species listed under the Act.

Certain critical habitat units for other listed species in the vicinity of CTS in Santa Barbara County may overlap with the critical habitat units designated for the California tiger salamander. This is the case with the final critical habitat designation for the La Graciosa thistle (*Cirsium loncholepis*). However, the habitat components essential for conservation (PCEs) differ for each of these species (for detailed information on the PCEs for the La Graciosa thistle, see the Primary Constituent Element section of the final rule (March 17, 2004, 69 FR at 12559); for detailed information on the PCEs for the CTS in Santa Barbara County, see the Primary Constituent Element section of this rule). The habitat components essential for conservation of the La Graciosa thistle identified in the final critical habitat rule would aid in protection of California tiger salamander aquatic habitat, but the proposed rule does not include a sufficient amount of upland habitat to sustain a viable population of California tiger salamanders (69 FR 12559). Therefore, the critical habitat proposed for the La Graciosa thistly does not afford adequate protection for the CTS in Santa Barbara County.

Critical habitat has recently been proposed for the California red-legged frog (*Rana aurora draytonii*) (April 13, 2004, 69 FR at 19626). A portion of the California red-legged frog proposed critical habitat (Unit 24, Santa Ynez River Unit) overlaps with the CTS in Santa Barbara County critical habitat (Unit 6, Santa Rita Valley). The habitat components essential for conservation of this species identified in the proposed California red-legged frog rule would aid in protection of California tiger salamander aquatic habitat, but the proposed rule does not include a sufficient amount of upland habitat to sustain a viable population of California tiger salamanders (69 FR 19627). Therefore, the critical habitat proposed for the California red-legged frog does not afford adequate protection for the CTS in Santa Barbara County.

Comment (12): One commenter was concerned with potential loss of land value in urban areas or areas designated for development.

Our Response: The economic analysis states that, because only about 1 percent of the real estate supply in Santa Barbara County is likely to be set aside

for the CTS in Santa Barbara County, offsetting compensation measures are not expected to have a significant impact on the dynamics of the regional real estate market. While real estate market values may temporarily decline following designation due to the perception that critical habitat designation may impose additional regulatory burdens on land use, we expect any such impacts to be short term. Additionally, critical habitat designation does not preclude development of Habitat Conservation Plans (HCPs) and issuance of incidental take permits. Landowners within the boundaries of this critical habitat designation will continue to have the opportunity to use their property in ways consistent with the conservation of the CTS in Santa Barbara County. Therefore, we believe that, because of (1) the high degree of public awareness of the species in northern Santa Barbara County, (2) the prohibition against take of the species both within and outside of the designated critical habitat areas, and (3) the small percentage of the Santa Barbara County real estate supply involved, property values are not likely to be affected by the critical habitat designation in the long term.

Issue 3—Property Rights

Comment (13): Several commenters expressed concern that the critical habitat designation would limit their land use practices or result in the loss of their lands. Specifically, one commenter stated that the government is proposing to condemn this private land or reduce its value to the owners. Another commenter stated that this rule would deny ranchers and farmers the use of their land. Another commenter was concerned that the designation would result in the loss of prime agricultural soils that are intensely farmed. One commenter was concerned with potential limits on irrigation and soil compaction. One commenter stated a concern regarding the additional time and money that would be needed in areas designated as critical habitat for oil spill cleanup.

Our Response: These comments reflect a misunderstanding of regulatory effect of critical habitat designation. Critical habitat designations do not constitute a burden in terms of Federal laws and regulations on private landowners carrying out private activities. Unless a Federal approval or permit is required, or Federal funds are involved with a project proposed on private property, the critical habitat designation poses no regulatory burden for private landowners, and in particular, should not affect farming and ranching activities on private lands. Similarly, absent a future Federal nexus, the designation should not affect future land use plans. Routine ranching activities are also exempt from take under the 4(d) rule.

While the designation of critical habitat does not constitute a regulation of private lands, the listing of the CTS in Santa Barbara County under the Endangered Species Act may affect private landowners. Actions which could result in take of California tiger salamanders (*e.g.*, ground disturbing activities such as soil compaction or soil remediation activities) require an exemption from take following consultation under Section 7 or and incidental take permit under section 10 of the Act. Because the CTS in Santa Barbara County was listed in 2000, proposed actions on private lands that require Federal authorization or funding that may affect the species already undergo consultation under Section 7 to ensure that their actions are not likely to jeopardize the continued existence of the species. Future consultations involving private lands will also analyze the effect of the proposed action on designated critical habitat.

The Act also requires recovery planning for listed species. Recovery planning for CTS in Santa Barbara County may include recommendations for land acquisition or easements involving private landowners. These efforts would be undertaken with the cooperation of the landowners. We also work with landowners to identify activities and modifications to activities that will not result in take, to develop measures to minimize the potential for take, and to provide authorizations for take through section 7 and 10 of the Act. We encourage landowners to work in partnership with us to develop plans for ensuring that land uses can be carried out in a manner consistent with the conservation of listed species and will continue to do so following the designation to preserve the conservation value of critical habitat while compatible development proceeds.

Issue 4—Mapping Methodology

Comment (14): Several commenters stated that the acreage proposed to be designated as critical habitat was too extensive.

Our Response: We used the best scientific data available in the designation of critical habitat for the CTS in Santa Barbara County, as per section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12. The areas we are designating as critical habitat have the physical and biological features (primary constituent elements or PCEs) that are essential to the conservation of the CTS in Santa Barbara County and that may require special management or protections. Few populations of the California tiger salamander exist in Santa Barbara County, and the threats to these populations are substantial. The six areas we are designating as critical habitat are essential to conserve these populations and to the overall conservation of the species. Each of the three peer reviewers agree that the areas we are designating as critical habitat provide for the essential life-cycle needs of the California tiger salamander and provide the habitat components essential for the conservation (PCEs) of this species. One of the three believes that the area included in the critical habitat designation should be expanded to include unoccupied areas in some cases.

Comment (15): Several commenters referred to additional acreage or, specifically, an additional 4,000 ac (1,619 ha) being protected for the CTS in Santa Barbara County by this designation.

Our Response: We are not aware of the acreage or area to which the commenters are referring. To our knowledge, no lands in Santa Barbara County are currently set aside for the protection of the California tiger salamander.

Comment (16): One commenter stated that lines drawn on the map are arbitrary. Another commenter stated that the acreage proposed for critical habitat has not been substantiated.

Our Response: Our Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (59 FR 34271) and our U.S. Fish and Wildlife Service Information Quality Guidelines (2002) provide criteria, establish procedures, and provide guidance to ensure that our decisions represent the best scientific and commercial data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

In determining areas that meet the definition of critical habitat for the CTS in Santa Barbara County, we used the best scientific and commercial data available. We have reviewed the overall approach to the conservation of the CTS in Santa Barbara County recommended to us by the science subteam of the recovery team for the CTS in Santa Barbara County (Service files 2002–

2003). We have also reviewed available information that pertains to the habitat requirements of this species. This material includes: data in reports submitted during section 7 consultations and by biologists holding section 10(a)(1)(A) recovery permits, research published in peer-reviewed articles and presented in academic theses and agency reports, and regional GIS coverages. Few populations of the California tiger salamander exist in Santa Barbara County and the protection of these populations is essential to the survival and recovery of the species as a whole. The six areas we are designating as critical habitat contain the essential primary constituent elements for the conservation of these populations and for the conservation of the entire species.

Comment (17): One commenter stated that Unit 4 includes approximately 27 ac (11 ha) of cultivated vineyards directly south of Hwy 101 which should not be included in the critical habitat designation.

Our Response: Vineyards can be used by California tiger salamanders for dispersal purposes (*i.e.*, they provide connectivity between aquatic and upland habitats) and, if small mammal burrows are present, sheltering and foraging. The 27 ac (11 ha) of cultivated vineyards in Unit 4 provide essential connectivity between the known ponds within that critical habitat unit.

Comment (18): One commenter opposed the inclusion of the Foley property, which is located on the edge of Unit 6 (Santa Rita Valley). This land is in existing vineyards. The commenter presumed that this inclusion was the result of a mapping error.

Our Response: This vineyard was included as a result of a mapping error. We have removed this vineyard in the final critical habitat map for Unit 6.

Comment (19): One commenter requested that Highway 246 and its shoulders be excluded from the designation.

Our Response: We have removed Highway 246 and its shoulders (or ROWs) from this designation (see Criteria Used To Identify Critical Habitat section).

Comment (20): One commenter stated that it is unclear what is meant by ''must hold water for a minimum of 12 weeks.''

Our Response: We needed to specify a timeframe to identify how long water should remain in these ponds in order to support successful California tiger salamander metamorphosis. Twelve weeks was selected as the minimum ponding interval that will allow at least some California tiger salamanders to metamorphose. This assumes that eggs are laid late in the season when water temperatures are higher and development occurs at the maximum rate. When eggs are laid in November through January at lower water temperatures, California tiger salamanders probably cannot metamorphose within 12 weeks. Our goal in setting this criterion is to separate those ponds that, in an average or better year, can potentially produce California tiger salamander metamorphs from those ponds that are too ephemeral to be successful breeding sites in any but the wettest years.

Comment (21): One commenter asked what period of time is used to determine a year of ''average'' rainfall. The commenter asked how we determined that a particular site retained water for 12 weeks during a year of average rainfall. The commenter asked if there is a reference year when rainfall was at or near average. The commenter asked what the source is for the rainfall and aquatic habitat site information.

Our Response: Rainfall is commonly calculated using the average rainfall for the rainy season rather than for a full calendar year. In California, precipitation generally occurs from late fall to early spring. Average rainfall for northern Santa Barbara County for the 1948–1949 through 2002–2003 rainy seasons averaged about 12.9 inches (in) (32.8 centimeters (cm)) (range, 4.3 in (10.9 cm) in 1971–1972 to 32.5 in (82.6 cm) in 1997–1998) based on the rainfall station at Santa Maria, California (*http://www.wrcc.dri.edu/summary/climsmsca.html*). We did not base our approach on a ''reference year.'' Our goal was to separate those ponds that, in an average or better year, can potentially produce California tiger salamander metamorphs from those ponds that are too ephemeral to be successful breeding sites in any but the wettest years. A pond that dries quickly in a ''dry'' year may still represent good habitat in a wetter year. Our minimum 12-week requirement is based on observations by Sam Sweet in Santa Barbara County (Dr. Sam Sweet, University of California at Santa Barbara, pers. comm. 2004). Similarly, Feaver (1971) reported that in Fresno County metamorphs leave pools 60 to 94 days (about 8–12 weeks) after eggs were laid. However, the length of time needed can be much longer in other parts of the range of the California tiger salamander. For example, in Monterey County metamorphs almost universally remained in ponds until May 1 (approximately 120 days (about 17 weeks) after eggs were laid) (Peter Trenham, U.S. Geological Survey, pers. comm. 2004).

Comment (22): One commenter asked what the time frame is for a potential pool site to be considered viable or ''essential,'' and at what point does that expire (*e.g.*, what if a pond held water for 12 weeks one time 7 years ago?). After how many years of below-average rainfall does a site become excluded from ''aquatic habitat?''

Our Response: As previously stated, a pond that dries quickly in a ''dry'' year may still be good habitat in a wetter year. With this designation, we did not include habitats that are too short lived. We have no examples of sites that are not considered aquatic habitat for California tiger salamanders in Santa Barbara County because they have not held water for long periods of time. Because we have no examples of such circumstances, we have not specified a time frame which might apply.

Comment (23): One commenter asked what grade or level is the cutoff point in elevation that is considered to be too steep for salamanders to cross.

Our Response: We did not use a specific criterion in terms of degrees of slope in our analysis because of the complex interaction between variables. In general, we used slope as a surrogate estimator for soil depth and soil moisture retention, when combined with knowledge of vegetation, aspect, and underlying geology. For example, an extensive south-facing hillside with chaparral and bedrock outcrops at a lesser slope might be excluded, whereas a north-facing slope with oaks and with greater slope might not be excluded. The south-facing slope might have too few small mammal burrows with too little residual soil moisture in late summer and fall, and thus, would not be suitable upland habitat for California tiger salamanders.

Comment (24): One commenter requested a detailed list of each type of vegetation that would be considered ''unsuitable'' and asked how dense this vegetation would need to be to exclude salamanders from passing through it or using the habitat around it.

Our Response: Regarding vegetation types, our specific goal was to include habitat that California tiger salamanders would clearly use (grassland, oak woodland, oak savanna, long-lasting ephemeral pools), and exclude habitats that were marginal and thus, not critical to the conservation of the species. However, because a patch or swath of marginal habitat nested within high quality habitat could not be excluded, most of these types of exclusions were made along the margins of units. Because of this type of site-by-site variation, it is not practicable for us to develop a complete list of index plants.

Regarding vegetation density, it is not practical for us to develop a specific criterion or vegetation thickness that would prevent salamanders from dispersing through vegetation. Density would be much greater to prevent dispersal in grassland habitat versus chaparral. We are unable to provide formal criteria to determine vegetation density due to the variation of vegetation present throughout the range of the California tiger salamander.

Comment (25): One commenter requested a detailed list of every type of geologic barrier that is excluded from the proposed critical habitat rule.

Our Response: An index of soil types or geologic formations cannot be developed because these categories (as formally defined by geologists, even at the finest scale of resolution) are rather broad. For example, lateral and vertical variation in the composition of the Paso Robles, or the Sisquoc, or the Careaga formations creates a range of suitable to unsuitable local soils, which is further complicated by slope, aspect, and geomorphological structure. The exact same bedrock on the crest of an anticline (a geological term for an arch of layered rock) will make for very different conditions than would occur at the bottom of a syncline (a trough of layered rock, opposite of an anticline). Because of these broad categories and variations in geological formations, we cannot provide an index of every type of geologic barrier.

Comment (26): One commenter requested a list of each and every type of agricultural barrier that would have no potential for restoration. The commenter asked how close an otherwise excluded agricultural barrier would need to be in order to be included because it is ''next'' to a known breeding pond. The commenter asked for clarification of the statement that an agricultural barrier would be included if it provided upland refugia for the California tiger salamander around a known pond. The commenter asked if this includes all or only some of the ''agricultural barriers.'' The commenter asked how the determination was made that an otherwise excluded agricultural barrier be included because it is important for connectivity between known breeding ponds. The commenter asked how large an area would need to be included to ensure connectivity between known breeding locations.

Our Response: We have already excluded agricultural barriers that we determined had ''no potential for restoration.'' For example, we drew boundaries that ran along the edge of agricultural fields. In addition, we excluded most, but not all, areas of frequently harvested agricultural lands. We determined which agricultural lands in association with known breeding ponds to include in the critical habitat designation on a site-by-site basis. We based our determination on the importance of agricultural land as either ''upland refugia'' (defined as the 2,200-ft (671 m) area surrounding a breeding pond) or as connectivity habitat between ponds. We did not consider agricultural lands more than 2,200 ft (671 m) from known breeding ponds to be upland refugia; therefore, we did not include them in critical habitat. We also excluded areas closer than 2,200 ft (671 m) if we determined that the areas did not contain the PCEs for the CTS in Santa Barbara County.

Using aerial photos, we also evaluated each agricultural area to identify barriers to California tiger salamander movements and agricultural areas of connectivity between breeding ponds. We considered ponds within 0.7 miles (mi) (1.1 kilometers (km) of each other to be within the dispersal distance of California tiger salamanders, therefore having connectivity value. If there was agricultural land between two ponds within 0.7 mi (1.1 km) of each other, we included the land because of its connectivity value unless there was a barrier that would prevent salamander movement between the ponds (*e.g.*, a heavily traveled highway). For a more detailed discussion, see the *Criteria Used To Identify Critical Habitat section*.

Accordingly, lands that are currently designated as critical habitat provide PCEs under current management practices. These lands were designated to provide protection from changes in management practices that would result in adverse modification of the critical habitat.

Comment (27): One commenter requested a complete list of each and every ''other'' type of land that is ''unlikely to contain PCEs essential for California tiger salamander conservation'' so that this criteria can be replicated by a person outside of the Service.

Our Response: It is not practicable for us to develop a complete list of each and every ''other'' type of land that is unlikely to contain PCEs. Determining if specific lands within the critical habitat boundaries do not have the PCEs for the California tiger salamander boundaries will have to be conducted on a case-by-case basis. We excluded areas that we could identify do not contain PCEs for the California tiger salamander. However, the PCEs for the California tiger salamander include lands essential for connectivity. Some lands which do not appear to provide suitable breeding or foraging habitat for the California tiger salamander are essential for connectivity (*i.e.*, cultivated land). Protecting the ability of California tiger salamanders to move freely across the landscape in search of breeding ponds is essential in maintaining gene flow and for recolonization of sites that are temporarily extirpated.

Comment (28): One commenter requested a detailed map of all ponds throughout the range of the CTS in Santa Barbara County. The commenter requested a copy of the science or references that were used to make this determination.

Our Response: The California Tiger Salamander Habitat map can be purchased through the County of Santa Barbara (South Coast, 123 East Anapamu Street, Santa Barbara, CA 93101–2058; North Coast, 624 W. Foster Road, Santa Maria, CA 93455–3623). The map was created in spring of 2000 by biologists who had conducted California tiger salamander surveys throughout Santa Barbara County (references provided with map).

Comment (29): One commenter requested that the land ratio formula be re-evaluated on the basis of individual applications rather than a ''one shoe fits all'' approach.

Our Response: We did not use a ''one shoe fits all'' approach. Rather, we evaluated lands within each unit separately, using the best scientific and commercial data available, to determine areas that best provide essential habitat for the California tiger salamander (see also response to comment 16). For each unit, we used 2,200 ft or 350 ac as a guide for the amount of upland habitat around known breeding locations to be mapped as critical habitat for the purposes of preserving California tiger salamanders within small mammal burrows (PCE 2). However, although various studies provide an approximation of the distances that California tiger salamanders can move from their breeding ponds in search of suitable upland refugia, we recognize that upland habitat features will influence California tiger salamander movements in a particular landscape. Therefore, where we had site-specific information on those features such as land use, topography, and geologic landform, we altered critical habitat lines to reflect that information.

Comment (30): One commenter suggested including additional unoccupied habitat in the final rule, such as pond watersheds, upland dispersal and burrowing areas, and

potentially suitable breeding ponds that are not occupied.

Our Response: Although one peer reviewer stated that including some unoccupied areas in the designation would be appropriate, the other peer reviewers agreed with our approach of including occupied areas only and stated that the areas we are designating provide for the essential life-cycle needs of the species, and provide the habitat components essential for the conservation (PCEs) of this species. Based on recommendations from the science subteam of the recovery team for the CTS in Santa Barbara County (Service files 2002–2003), and our analysis of the best available scientific and commercial data, we determined that these areas or units provide for the essential life-cycle needs of the species, and provide the habitat components essential for the conservation of the California tiger salamander. Therefore, we do not believe that it is necessary to the conservation of the California tiger salamander to designate critical habitat in unoccupied areas.

Comment (31): One commenter stated that the Service failed to explain why the one known pond in Unit 6 (Santa Rita Valley) was left out of the designation and why it is not considered essential to the conservation of the California tiger salamander. The commenter stated that, although the pond is isolated, it is one of the two known breeding populations in that valley and should be included.

Our Response: This pond likely has little or no connectivity due to the distance between it and other known or potential breeding ponds (over 2 miles), which is further than California tiger salamander dispersal distance. In addition, this pond occurs in a separate drainage and is separated from the other ponds by a steep ridge. Because of the isolation of the human-made pond in Unit 6, we do not believe it contains the primary constituent elements for the California tiger salamander and did not include it within the boundaries of critical habitat.

Issue 5—Economic Analysis

Comment (32): One commenter stated that, as written in the proposal, the economic analysis of effects is biased regarding small businesses.

Our Response: As set forth in our regulations found at 50 CFR 424.19, the economic analysis is conducted after critical habitat has been proposed in a given area. As required under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), we published a notice of rulemaking for this proposed rule, and we prepared and made available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). Please refer to the Required Determinations section contained in this final rule for more information.

Comment (33): Several commenters stated that an economic analysis should be completed and shared with the community prior to designating critical habitat.

Our Response: We routinely prepare a draft of the economic analysis (DEA) on proposed critical habitat rules and release it for public comment before issuing a final critical habitat rule. We released the DEA for the California tiger salamander in Santa Barbara County on October 7, 2004 (69 FR 60138) and accepted comments on the DEA from that date through November 8, 2004. This information has been used in our final determination.

Comment (34): A few commenters were concerned with the short timeline for the economic analysis to be completed. The commenters reiterated that the economic analysis needs to be accurate and complete.

Our Response: We frequently designate critical habitat under short, court-ordered deadlines. Even when our analyses are conducted under short time frames, we use the best scientific and commercial data available.

Comment (35): Several commenters stated that the public should have the opportunity to comment on the economic analysis.

Our Response: As part of the process by which all critical habitat rules are finalized, we solicit data and comments from the public on all aspects of critical habitat proposals, including data on the economic and other impacts of designation. We released the DEA for the California tiger salamander in Santa Barbara County on October 7, 2004 (69 FR 60138) and accepted comments on the DEA from that date through November 8, 2004.

Comment (36): One commenter recommended that the DEA follow the methodology used by the California Resource Management Institute in examining economic impacts resulting from critical habitat designation for the California Coastal Gnatcatcher.

Our Response: On August 15, 2003 the California Resource Management Institute (CRMI) released an economic analysis, authored by Dr. Sunding, of critical habitat designation entitled ''Economic Impacts of Critical Habitat Designation for the Coastal California Gnatcatcher'' (referred to as the CRMI study). The CRMI study relies on an economic model developed to assess the impacts of reductions in real estate product (e.g., residential and commercial buildings) in areas proposed for designation as critical habitat for the Coastal California Gnatcatcher.

Despite addressing a different critical habitat rulemaking, the California Tiger Salamander Draft Economic Analysis (CTS DEA) and the CRMI study share a number of important analytical and methodological similarities. First, both studies agree that the primary economic impacts to real estate will result from (1) reduced real estate development, (2) project modification and regulatory compliance costs associated with species conservation activities, and (3) project delay.

Second, both the CRMI approach and the DEA rely on demographic and land use projections obtained from public agencies to estimate future development pressure and the associated loss of development opportunities due to habitat set aside. Third, both approaches assume that all real estate development projects will be affected, regardless of the presence of a Federal nexus.

Finally, both approaches estimate the total costs of species conservation activities without subtracting the impact of pre-existing baseline regulations (*i.e.*, the cost estimates are fully co-extensive). It is important to note that in previous comparisons of the results of analyses prepared by the Service and CRMI, much of the difference in impact estimates resulted from the use of different assumptions regarding the necessity of a Federal nexus to generate costs and different assumptions about counting costs attributable co-extensively to baseline regulations (*i.e.*, in previous Service analyses baseline costs were not counted).

The DEA also includes a number of additional economic categories not evaluated in the CRMI study but these categories represent a relatively small component of the total economic impact (these include costs associated with California Environmental Quality Act (CEQA) as well as those incurred by viticulture, road construction, utilities and airport facilities).

Two analytical differences exist between the methodology applied in the DEA and the CRMI approach.

1. *Discounting:* The two studies apply a different approach to evaluating economic impacts that occur over time. Specifically, the DEA applies a positive real discount rate to costs that occur in the future to account for the affect of the

time value of money. In contrast, the CRMI study assumes that the real discount rate will equal real property appreciation, and thus the timing of development has no impact on economic value. (The CRMI study does assume a positive discount rate to calculate the economic impact of delay.)

2. *Consumer Surplus:* The DEA concludes that the California tiger salamander in Santa Barbara County critical habitat designation will primarily affect individual property owners/developers and not market prices or consumers of real estate. In contrast, CRMI study concludes that the Gnatcatcher critical habitat designation will lead to an increase in real estate market prices and thus a reduction in consumer surplus. The CRMI study calculates this reduction in consumer surplus and includes it in the total economic impact attributable to Gnatcatcher critical habitat designation.

Chapter 3 of the DEA evaluates the potential for the California tiger salamander in Santa Barbara County critical habitat designation to reduce consumer surplus by increasing real estate market prices. The analysis concludes that critical habitat designation will not affect regional real estate markets or prices, and thus consumer surplus, because the total reduction in land supply is expected to represent a very small component of total future market demand in the region. Specifically, the upper-bound estimate of developable acres of habitat set-aside within critical habitat designation is estimated at about 1.1 percent of future market growth in Santa Barbara County through 2030. Supply adjustments by developers, including increased density and/or project reconfigurations, are likely to further cancel the market impact of the relatively small land supply reduction created by critical habitat designation.

Comment (37): Two commenters states that the economic analysis needs to calculate the loss in future earnings (or lost investment) from land that can not be developed as a result of critical habitat designation.

Our Response: Potential earnings from real estate are reflected in real estate prices. Specifically, in a competitive market, the price of land is the best reflection of its future earning potential. The DEA calculates lost earnings from real estate by estimating land value losses associated with land that is projected to be dedicated as habitat rather than developed for profit. Specifically, the DEA assumes that each acre of projected real estate development within critical habitat designation will require 3 acres of land be set aside as habitat (*i.e.,* a 3-to-1 offsetting compensation ratio). The prevailing market value of the habitat set aside is lost when the land is designated as habitat because the land no longer has earning potential. Land value losses are described in Chapter 3 of the DEA and presented in Table 6.

Comment (38): One commenter stated that the DEA assumption of a 3-to-1 offsetting compensation ratio is an underestimate.

Our Response: The Service has not conducted a formal consultation concerning residential development effects on California tiger salamanders in Santa Barbara County and their habitat. The Service has conducted one consultation involving a construction project which involved only minimal habitat removal and no set-aside. Due to the lack of historical precedent, the DEA relies on an offsetting compensation ratio based on interviews with Service field biologists. The DEA acknowledges that actual offsetting compensation requirements are unknown but notes that the assumption of a 3-to-1 ratio is consistent with ratios resulting from consultations on other listed species with similar habitat needs and lies within the range of used in other critical habitat designation economic analyses. The actual offsetting compensation ratio used in any particular case will depend on a variety of factors unique to the circumstance at hand. The 3-to-1 assumption used in the DEA represents an average.

Comment (39): A number of comments state that the DEA does not rely on appropriate real estate values to estimate land value losses from critical habitat designations.

Our Response: To calculate land values for acreage expected to support at least one unit per acre, the DEA relies on the median sale price of a newly-constructed home in Santa Barbara County in 2004, as reported by DataQuick Information Systems. For acreage expected to support less than one unit per acre, the DEA relies on the median sale price of raw residential land in Santa Barbara County, as reported by DataQuick. As shown in Table 3 of the DEA, land values vary by the density of expected development. The Service maintains that DataQuick is an acceptable data source and that the Santa Barbara County market area is appropriate given the extent of the critical habitat designation.

Comment (40): One comment states that the land value appreciation forecasted by the DEA is overly optimistic.

Our Response: To estimate future appreciation in home values, the DEA relies on long-term historical trends which are appropriate for the 26-year forecast utilized by the DEA. In particular, the DEA relies on the average of a 10-year and a 20-year trend of repeat sales and refinancing of the same properties in California. The price indexing of the same properties over time controls for potential changes in housing quality, location and size over time. These data were obtained from U.S. Department of Labor, Office of Federal Housing Enterprise Oversight.

Comment (41): In order to quantify lost development opportunities within critical habitat designations, the DEA must rely on a projection of future demand for real estate within critical habitat designations. One commenter stated that the use of aggressive growth projections is arbitrary and that 100 percent buildout is not realistic. Further, the comment states that in-fill is likely to offset development in ''greenfield'' areas.

Our Response: The DEA endeavors to estimate economic impacts of a critical habitat designation using a conservative (*i.e.,* overestimate rather than underestimate) approach. For this reason, the analysis relies upon aggressive development projections, generated by Santa Barbara County Planning and Development, which suggest that full buildout is realistic. It should be noted that the full buildout scenario relied upon by the DEA assumes that on-site habitat set aside for California tiger salamander reduces the development possible within a critical habitat designation. The assumption that in-fill will not satisfy projected demand is also made in an effort to estimate impacts conservatively.

Comment (42): Two commenters stated that urban growth boundaries in Santa Maria and Orcutt may prevent development projected by the DEA.

Our Response: The legal requirements of the growth boundary ordinances are complex and it is unclear how they may limit real estate development over the long term. For example, the Orcutt Community Plan allows for changes in growth limitations if in-fill development opportunities begin to disappear. In an effort to conservatively estimate the economic impacts resulting from forgone real estate development, the DEA implicitly assumes that local policies regarding growth will adapt to satisfy real estate demand as forecasted by the County.

Comment (43): One comment states that the fractional ownership of land within CHD may result in project infeasibility due to offsetting compensation for impacts.

Our Response: While fractional land ownership may impair project feasibility in some cases, the Service maintains that economic losses are accurately measured. A number of options are available to project proponents unable to go forward with a project due California tiger salamander conservation measures, including (1) buy adjacent land for habitat set-aside for project expansion, (2) buy off-site land for habitat set-aside or (3) scale the project to allow for habitat set-aside. Over the long term it is very unlikely that any land parcel will be rendered totally useless by a critical habitat designation (a feasibility study of each parcel within critical habitat is beyond the scope of the DEA). While additional transaction costs and planning costs may be incurred, these additional costs are likely to be minor relative to the loss in land value captured by the DEA.

Comment (44): One commenter stated that development projects currently undergoing the planning process are not sufficiently considered by the DEA.

Our Response: The DEA does not examine each future development project individually. Future development forecasts are based on aggregate-level growth projections provided by Santa Barbara County Planning and Development. This approach allows the Service to estimate impacts farther into the future (*i.e.*, 26 years) than a method that relies on assessing currently planned projects. Although not identified by name, impacts to development projects such as the Bradley Ranch are included in the DEA estimates, because these projects represent the fulfillment of near-term growth projected by the County.

Comment (45): One commenter suggested that economic impacts should be estimated in perpetuity.

Our Response: Page 17 of the DEA states that ''the analysis looks prospectively at future costs associated with the listing, critical habitat, and other related (California tiger salamander) protections * * * based on activities that are ''reasonably foreseeable,'' including but not limited to activities that are currently authorized, permitted or funded, or for which proposed plans are currently available to the public.'' The DEA time horizon corresponds to available population and housing forecasts available from Santa Barbara County. The Service does not have sufficient data to estimate future impacts in perpetuity with any level of certainty. However, it should be noted that land value losses represent losses in perpetuity since property values account for potential earnings in perpetuity.

Comment (46): One commenter stated that development of all second tier agricultural land by 2015 is unlikely.

Our Response: Page 35 of the DEA states that ''Second-tier agricultural lands are assumed to convert to residential use * * * beginning in 2015'' and that this ''allows 10 years for agricultural preservation contracts (*i.e.*, Williamson Act) to be cancelled.'' The 2015 date indicates when contracts will begin to expire. The analysis does not assume that all second-tier agricultural lands will be developed by 2015, but rather that they will develop between 2015 and 2030.

Comment (47): Various commenters suggested that the impacts of CHD on the CEQA process for projects located within CHD are not estimated correctly, some stating that costs are overstated and others asserting that they are understated.

Our Response: The DEA estimates CEQA-related costs by assuming that projected future projects that might have qualified for a negative declaration or an exemption under CEQA will undergo an Environmental Impact Report and experience higher CEQA costs after a critical habitat designation. The elevated CEQA review and associated cost is attributable to new information provided by a critical habitat designation. Projected future projects are based on historical CEQA trends in Santa Barbara County, as reported by the State of California's CEQAnet database. Costs associated with various CEQA documents are based on interviews with a number of consulting firms specializing in CEQA analyses (see footnote 39 in the DEA for the names of these firms).

Comment (48): One commenter stated that project delay would not result from CHD.

Our Response: The DEA does not assume that all projects will experience delays. Rather, the DEA calculates delay costs based on the assumption that only projects commencing in the first year after a critical habitat designation will experience delays. These projects may not have planned to conduct California tiger salamander conservation activities. Projects beginning more than 12 months after a critical habitat designation will avoid delay by incorporating consideration of a critical habitat designation in standard project planning.

Comment (49): One commenter called into question the use of a 7 percent discount rate.

Our Response: The most current Office of Management Budget (OMB) guidance on discounting practices to be used in regulatory analysis is provided in OMB Circular A–4.[1] OMB circular A–4 states the following:

> ''* * * A real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector.'' [2]

Comment (50): One commenter stated that cattle grazing impacts should be addressed.

Our Response: Impacts to cattle ranching are addressed on page 50 of the DEA.

Comment (51): One commenter stated that the DEA fails to consider the multiplier effects associated with lost investment opportunities as the critical habitat designation affects industry, residential, commercial, retail, and agricultural land uses.

Our Response: Indirect ''multiplier'' effects are sometimes used to analyze the impact of major development projects or other economic activities on an economic region, often defined as a county or multi-county area. The localized nature of critical habitat designations makes analysis using multipliers difficult, because multiplier data is unreliable at the sub-county level. In addition, real estate development, the primary sector expected to be affected by a critical habitat designation, is unlikely to be affected at the county level (see discussion in Chapter 3 of the DEA). That is, although construction activity may be redistributed throughout Santa Barbara County as a result of CHD, it is not expected to decline overall.

Comment (52): Several commenters stated that the DEA inadequately addresses impacts to small businesses.

Our Response: Appendix A analyzes impacts to small businesses in the land development and viticulture sectors. As described in this appendix, the DEA uses the best available data to identify the number of firms that might be affected by the critical habitat designation and to estimate impacts to those firms based on estimates of total impacts. Because it is nearly impossible to identify the specific small businesses

[1] Executive Order 12866, ''Regulatory Planning and Review,'' September 30, 1993; U.S. Office of Management and Budget, ''Circular A–4,'' September 17, 2003, available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.*

[2] Ibid.

that will undertake development and viticulture projects within the critical habitat designation over a 26 year period (*e.g.*, 115 small developers currently exist in Santa Barbara County), the assumptions relied upon in the analysis are reasonable.

Comment (53): One commenter stated that the DEA fails to fully consider impacts associated with highway maintenance, such as us 101, Highways 246 and 135, which run through the middle of the critical habitat designation.

Our Response: The primary focus of the DEA is to provide decision makers with an estimate of the impacts associated with the proposed rulemaking. Understanding the magnitude of historical impacts helps decision makers place future costs in context. The DEA estimates historical costs associated with viticulture, road construction, utilities and infrastructure projects, and the airport district development project using the best publicly-available data (see Chapters 4 and 5 of the DEA).

Comment (54): A number of commenters stated that the DEA underestimates the historical cost of California tiger salamander conservation measures.

Our Response: The primary focus of the DEA is to provide decision makers with an estimate of the impacts associated with the proposed rulemaking. Understanding the magnitude of historical impacts helps decision makers place future costs in context. However, because historical costs are not directly relied upon for decision making, a less precise cost estimate is acceptable.

Comment (55): One commenter stated that costs associated with re-planning projects originally intended for critical habitat areas are not captured by the analysis.

Our Response: While some current projects may incur additional planning costs, future projects will be aware of habitat constraints before the planning process begins. For this reason, additional planning costs are expected to be minor.

Comment (56): Numerous comments state that costs associated with litigation are not estimated by the DEA.

Our Response: It is likely that potentially affected parties may incur administrative costs related to review of Federal documents such as the Proposed Rule in order, for example, to ensure their activities are appropriately considered in the economic analysis, or to request exemption from the rulemaking. The DEA considers only the direct and indirect costs associated with compliance with the rulemaking. The DEA does, however, include administrative costs of compliance with the rulemaking where appropriate, for example the administrative costs of section 7 consultation, which may similarly include review of Federal documents. In addition, the DEA focuses on activities that are considered reasonably foreseeable. The number, scope and timing of potential legal challenges associated with the rulemaking is difficult to quantify.

Comment (57): Two commenters stated that costs associated with CTS conservation activities undertaken by public entities may result in an increased tax burden for the community.

Our Response: While economic impacts born by the public sector are captured by the DEA, it is unclear if or how various jurisdictions might pass on their increased costs to taxpayers. However, it is important to note that these tax policy and cost allocation decisions are regarded as distributional rather than economic welfare effects. Given the high level on uncertainty associated with future tax and spending policy at the local and State level, The DEA does not forecast these effects.

Comment (58): One comment states that the DEA limits its analysis of agricultural impacts of the critical habitat designation to viticulture.

Our Response: The DEA addresses impacts to agriculture in Chapter 4. Grazing activities are assumed to proceed as they do currently, a point bolstered by the Service's special rule, authorized under section of 4(d) of the ESA, to work cooperatively with ranchers. The DEA assumes that prime agricultural lands will not be affected by the critical habitat designation as these cultivated lands are not suitable habitat for California tiger salamander. In addition, the DEA estimates that all secondary agricultural land will be developed during the period of the study (Chapter 3), which results in higher costs than if habitat set-asides were applied to agricultural land. Finally, costs associated with vineyard conversion are calculated and presented in Tables 11 and 12.

Comment (59): One commenter stated that the DEA should evaluate the impact of the critical habitat designation on conversions of rangeland to dry and irrigated crops.

Our Response: The California tiger salamander consultation history does not contain any biological opinions addressing rangeland conversion to field crops. Given the lack of historical consultations, the DEA does not calculate any impact resulting from this project type. The Service will evaluate such conversions, if they occur, on a case-by-case basis. Impacts related to vineyard conversion resulting from the critical habitat designation are calculated in Chapter 4 of the DEA.

Comment (60): One commenter stated that the DEA should account for the impact of the critical habitat designation on CEQA costs for agriculture projects.

Our Response: While the critical habitat designation will provide new information regarding California tiger salamanders in agricultural areas, it is unlikely that small agriculture projects would be required to prepare an Environmental Impact Report due to the critical habitat designation alone.

Comment (61): One commenter stated that the DEA does not reflect any of the major economic benefits that would accrue to Santa Barbara County if the county was excluded from the critical habitat designation.

Our Response: The economic impacts presented in the DEA reflect the estimated cost of the proposed critical habitat designation. Any areas that are excluded from the proposed designation (in the final designation) would avoid such impacts, which could be construed as the associated benefit, or cost avoidance.

Comment (62): One commenter asked how will the Department consider economic impacts as part of the overall final designation.

Our Response: Section (4)(b)(2) of the Act requires the Service to designate critical habitat on the basis of the best scientific data available, after taking into consideration the economic impact and any other relevant impact, or specifying any particular areas as critical habitat. The Service may exclude areas from the critical habitat designation when the benefits of exclusion outweigh the benefits of including the areas within critical habitat, provided the exclusion will not result in the extinction of the species. The Service uses the information in the economic analysis to determine whether it should consider areas for exclusion for economic reasons.

Comment (63): One commenter stated that the DEA falsely assumes that small rural residential development projects will not be subject to land set-asides.

Our Response: The economic analysis shows total efficiency costs for the species in Santa Barbara County. Project modification and administrative costs are those costs associated with implementing species and habitat management efforts. These costs include the cost of offsetting compensation (*i.e.*, land set-aside) for impacts to California tiger salamander habitat. Additionally

project modifications include minimization and avoidance measures to protect the California tiger salamander when a project in ongoing. Land set-asides make up the large majority of the total project modification cost. Estimation of the regional significance of land set-aside suggests that regional real estate markets will not be affected by California tiger salamander conservation efforts. One of the key assumptions of this analysis, see Exhibit ES–4, is the analysis does not assume that developers may satisfy multiple public land use requirements by setting aside California tiger salamander habitat on the project site. In reality, projects benefit from claiming that habitat protection provides open space, necessary buffering between incompatible land uses, flood control, and other functions. The use of habitat land in this way reduces the projects required dedication of land for other open space uses compared to a land use plant in which no habitat set aside is required. As shown in Table 2 ''Summary of Future Development Set-Aside within Proposed CTS CH (2005–2030)'' of the DEA, footnote (3) states ''* * * Note that some low-density land uses (*e.g.*, rural residential) are assumed to not require land set-aside.

Comment (64): One commenter stated critical habitat requirements overlap with other requirements that promote open space and thus should not be entirely accounted for as an impact; the commenter expressed concern that the estimates contained in the DEA inappropriately include costs associated with existing land-use requirements that serve to promote open space.

Our Response: The primary purpose of the economic analysis is to estimate the impact of actions take to protect the federally listed California tiger salamander and its habitat. It attempts to quantify the economic effects of the designation of critical habitat, as well as the economic effects of protective measures taken as a result of the listing of the California tiger salamander. The economic analysis also complies with the direction from the U.S. 10th Circuit Court of Appeals, that, when deciding which areas to designate as critical habitat, the economic analysis informing that decision should include ''co-extensive'' effects. The DEA discusses other relevant regulations and protection efforts as the protection of the California tiger salamander and its habitat is not limited to the Act. In general, this analysis errs on the side of conservatism in order to make certain the economic effects have not been missed. It treats as ''co-extensive'' other federal and State requirements that may result in overlapping protection measures (*e.g.*, section 404 of the Clean Water Act, and the California Environmental Quality Act). In some cases, however, non-habitat related regulations will limit land use activities within critical habitat in ways that will directly or indirectly, benefit the California tiger salamander or its habitat (*e.g.* , local zoning ordinances). These impacts were not considered to be ''co-extensive'' with the California tiger salamander listing or designation.

As stated in the DEA, 280, ''This analysis also endeavors to capture the net economic impact imposed on regulated entities, and the regional economy resulting from California tiger salamander conservation efforts. To the extent possible, the estimated net economic impact should account for any offsetting benefits that might accrue to the regulated community due to their habitat preservation activities. For example, in certain cases real estate development that effectively incorporates California tiger salamander habitat set-aside on-site might realize a value premium typically associated with additional open space. Any such premium will offset land preservation costs borne by landowners/developers. Unfortunately, reliable data revealing the premium that the market places on nearby open space in Southern California is not readily available. Moreover, the value premium associated with habitat preservation is likely to be limited given that the recreational uses associated with habitat preserves are generally restricted.''

Comment (65): One commenter stated that DEA for the critical habitat designation for the California tiger salamander in Santa Barbara County does not identify and assess benefits.

Our Response: The DEA, 440, Benefits section, states ''Given the limitations associated with estimating the benefits of proposed critical habitat designation for the California tiger salamander, the Service believes that the benefits of proposed critical habitat designations are best expressed in biological terms that can be weighed against the expected cost impacts of the rulemaking.'' The development of quantitative estimates associated with the benefits of critical habitat is impeded by the lack of available studies and information relating to the size and value of beneficial changes that are likely to occur as a result of listing a species or designating critical habitat.

This analysis is used for helping the Service to decide whether to exclude areas and whether the exclusions outweigh the conservation benefits of inclusion. So, the economic analysis looks at the burden on the public of the regulation, and whether any areas have a disproportionate burden. The Service must then balance that against the benefits of including that area—including the benefits of the area to the species and the benefits of the species' existence and recovery. We do this in the 4(b)(2) discussion in our rules. We believe that monetizing may trivialize the benefits of critical habitat because there are no widely accepted ways for placing a dollar value on a biological benefit. In this analysis, several categories of benefits were identified, including preservation of open space and biodiversity, both of which are associated with species conservation.

Comment (66): One commenter stated that the area within Unit 1(Western Santa Maria/Orcutt), east of Black Road, and the area within Unit 2 (Eastern Santa Maria), west of Telephone Road, should both be excluded because of proposed future growth and development plans.

Our Response: Section (4)(b)(2) of the Act requires the Service to designate critical habitat on the basis of the best scientific data available, after taking into consideration the economic impact and any other relevant impact, or specifying any particular areas as critical habitat. The Service may exclude areas from the critical habitat designation when the benefits of exclusion outweigh the benefits of including the areas within critical habitat, provided the exclusion will not result in the extinction of the species. Based on the Service's analysis of the best available scientific and commercial data, we determined that these areas or units provide for the essential life-cycle needs of the species. The draft economic analysis shows that Units 1 or 2 carry over 98 percent of total estimated costs ($418.3 million) for 52 percent of the total proposed acreage.

Unit 1 (Western Santa Maria/Orcutt) is essential to the conservation of the California tiger salamander because it contains 37 percent of the natural vernal pools for this population. Unit 1 contains 7 (approximately 37 percent) of the 19 natural vernal ponds that occur in Santa Barbara County. ften, natural ponds do not require as much, if any, maintenance whereas artificial ponds require continual maintenance (*e.g.*, berm repair, erosion control, sediment removal activities). Collectively, Unit 1 contains 12 known California tiger salamander breeding ponds and several water bodies that are suitable for breeding California tiger salamanders but that have never been surveyed. The 12 known breeding ponds in this unit constitute approximately 26 percent of

the known breeding ponds (46) in Santa Barbara County.

Unit 2 (Eastern Santa Maria)) is essential to the conservation of the California tiger salamander because it contains 21 percent of the natural vernal pools used for California tiger salamander breeding in Santa Barbara County (19 natural vernal ponds total). The unit contains 4 known California tiger salamander breeding ponds and additional water bodies that are suitable for breeding California tiger salamanders but that have never been surveyed. All four known breeding ponds in Unit 2 are natural vernal pools. As mentioned in the above description for Unit 1 (Western Santa Maria), often, natural ponds do not require as much, if any, maintenance whereas artificial ponds require continual maintenance (*e.g.*, berm repair, erosion control, sediment removal activities).

Comment (67): One commenter stated that the Service needs to reevaluate the critical habitat designation because the California tiger salamander no longer constitutes a DPS and as a result needs to conduct a new and revised economic analysis; Another commenter stated the economic analysis needs to consider the potential impacts across the entire range of the species (186,840 acres) rather than just the critical habitat designation's proposed designation of 13,920 acres.

Our Response: On January 22, 2004, we proposed six units comprised on 13,920 in total for the California tiger salamander in Santa Barbara County (69 FR 3064). At the time this analysis was conducted, the California tiger salamander was listed as a DPS and we looked at the 13,920 acres proposed as critical habitat. Exhibit ES–1 of the draft economic analysis details the description and acreage of each unit. The purpose of the draft economic analysis report is to identify and analyze the potential economic impacts associated with the designation of critical habitat for the California tiger salamander in Santa Barbara County. The geographic scope of the economic analysis focuses on the area being proposed for designation in northern Santa Barbara County, and not the entire range of the species. We will conduct an economic analysis for the California tiger salamander, Central population designation this fiscal year, and when we propose the Sonoma County portion of the California tiger salamander critical habitat, we will analyze the economic impacts of that portion of the designation.

Issue 6—Procedural Concerns

Comment (68): One commenter stated that the critical habitat designation is not determinable due to lack of sufficient information regarding the space needed for individual and population growth, and for normal behavior; the species requirements for food, water, air, light, mineral, or other nutritional or physiological needs; the amount of cover or shelter required; the locations for breeding, reproduction or rearing of offspring; nor the location of habitats that are protected from disturbance or that are representative of historic geographical and ecological distributions of the species.

Our Response: We believe that we have sufficient information to identify appropriately critical habitat for the California tiger salamander in Santa Barbara County. In our determination of the areas that meet the definition of critical habitat for the California tiger salamander, we used the best scientific and commercial data available (see also Response to Comment (16)).

Several published, peer-reviewed studies have been conducted relating to the California tiger salamander's biology and its habitat needs. Included in this information is how far they have been found to disperse (*i.e.*, space needed for individual and population growth and for normal behavior), the fact that they feed underground in small mammal burrows as adults and in aquatic habitat when juveniles (*i.e.*, the species requirements for food), the need for ponded water for breeding purposes (*i.e.*, the species' requirements for water and the locations for breeding, reproduction or rearing of offspring), and the fact that they spend most of their lives underground in small mammal burrows (*i.e.*, the amount of cover or shelter required). For more species information, please refer to the Background section of the proposed critical habitat rule (January 22, 2004, 69 FR 3064).

Comment (69): One commenter stated that the designation is not prudent due to the fact that the species continues to be threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species and such designation of critical habitat would not be beneficial to the species.

Our Response: According to our regulations at 50 CFR 424.12, a designation of critical habitat is not prudent when one or both or the following situations exist: (1) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species or (2) such designation of critical habitat would not be beneficial to the species. In the final rule listing the California tiger salamander in Santa Barbara County as endangered (September 21, 2000, 65 FR 57242), we found that a designation of critical habitat was prudent. Our reasoning is discussed in that final rule listing. We believe this rationale is still applicable.

Comment (70): Several commenters stated that no public input was used in the designation.

Our Response: The public is asked to provide comments on critical habitat proposals. The comments are fully considered as we make our final determination. We solicited data and comments from the public on all aspects of this proposal, including data on the economic and other impacts of designation. We had three public comment periods on the proposed rule (January 22, 2004, through March 22, 2004, April 13, 2004, through May 28, 2004, and October 7, 2004, through November 8, 2004). We also held a public hearing on our proposal to designate critical habitat for the Santa Barbara County population of California tiger salamanders on May 11, 2004, in Santa Maria, California. We conducted an informational meeting on March 10, 2004, in Santa Maria to discuss the methodology used to create the critical habitat units and what critical habitat means for landowners within the critical habitat boundaries. Written public comments were accepted at the public hearing and entered into the supporting record for the rulemaking. Oral comments given at the public hearings were also accepted into the supporting record. In making our decision on the critical habitat designation, we gave written comments the same weight as oral comments presented at hearings. See also *Summary of Comments and Recommendations* section above.

Comment (71): One commenter generally agreed with, and supported, the designation, and requested that the Service make available to the public which areas, if any, will be left out of the final rule at the same time the economic analysis is released for comment.

Our Response: Typically, we do not make a determination to exclude an area from final critical habitat based on economic considerations at the time the draft analysis is released. The determination is made at the end of the rulemaking process following our receipt and review of public comments on the proposed rule and draft economic analysis and following any

appropriate revisions to the draft economic analysis as we write the final critical habitat rule.

Comment (72): One commenter stated that much of the farming and ranching around these areas build and use stock ponds, which salamanders use. However, these increased restrictions might make it so no one would want to continue to do this or other soil conservation projects. Another commenter stated that this designation has the potential to discourage many wildlife friendly ranching practices and further hinder new and ongoing restoration and conservation efforts.

Our Response: We recognize the importance of landowner cooperation for conservation of listed species. This is true for the lands designated as critical habitat for the California tiger salamander, which are mostly under private ownership. We also recognize that critical habitat designations could potentially have a negative impact on voluntary partnerships with private landowners. Some landowners have been working with us to develop conservation easements on or Memoranda of Understanding for their properties to protect the California tiger salamander. These voluntary conservation efforts are not complete but are well under way. After weighing the benefits of including these areas as critical habitat with the benefits of excluding them, we concluded that the designation of critical habitat would have a net negative conservation effect in some situations, and we excluded those areas with completed Memoranda of Understanding regarding conservation actions from the final designation of critical habitat. See our discussion under the Relationship of Critical Habitat to Lands Implementing Approved Conservation Strategies below. We also acknowledged the importance of ranchlands to California tiger salamander conservation in our August 4, 2004, Special Rule exempting existing routine ranching practices from take of California tiger salamanders throughout the species' range (August 4, 2004, 69 FR 47212).

Comment (73): One commenter stated that the process for farmers and ranchers to obtain Federal funding through the Farm Bill is already too slow a process; the additional section 7 consultation would add more time to this.

Our Response: All lands designated as critical habitat are within the geographic area occupied by the species (based on observations made within the last 3 years), and are likely to be used by the California tiger salamander, whether for foraging, breeding, growth of larvae and juveniles, dispersal, migration, genetic exchange, or sheltering. Thus, we consider all critical habitat units to be occupied by the species. Federal agencies already consult with us on activities in areas currently occupied by the species or if the species may be affected by the action to ensure that their actions do not jeopardize the continued existence of the species. Therefore, we believe that the designation of critical habitat is not likely to result in significant additional regulatory burden above that already in place due to the presence of the listed species.

Comment (74): One commenter recommended that the Service use the economic analysis prepared by David Sunding, Aaron Swoboda, and David Zilberman of the Center for Sustainable Resource Development in the College of Natural Resources at UC Berkeley, titled ''The Economic Costs of Critical Habitat Designation: Framework and Application to the Case of California Vernal Pools'' for a more realistic look at the true costs of designating critical habitat.

Our Response: The Service has adopted numerous guidelines and procedures for developing critical habitat designations based upon the best information available. From time to time, these guidelines are altered, and we will consider any information that could make these designations more useful; however, we cannot adopt an outside source of guidance without considerable review and consideration. We appreciate the commenter's recommendation and will evaluate the referenced document for future critical habitat rules.

Comment (75): Several commenters stated that, if the Santa Barbara County DPS of the California tiger salamander is downlisted to threatened as proposed in the May 2003 proposal (68 FR 28648), this might affect the final critical habitat rule.

Our Response: Designation of critical habitat is required under the Act whether a species is threatened or endangered. In the final rule we have designated habitat in Santa Barbara County that is essential for the conservation of the California tiger salamander. Each of the six populations of California tiger salamander in Santa Barbara County is essential to the survival and recovery of the species as a whole and this designation covers the habitat essential to conserve those six populations. Because our August 4, 2004, determination listed the California tiger salamander rangewide as threatened and eliminated the separate Santa Barbara County and Sonoma County DPS designations (69 FR 47212), this final critical habitat designation will become part of the critical habitat ultimately designated for the species rangewide. We anticipate completing the critical habitat designation for California tiger salamander rangewide through future rulemaking. We proposed critical habitat for the central portion of the California tiger salamander's range (Central population) on August 10, 2004 (69 FR 48570).

Comment (76): One commenter referred to efforts being made by the Service and stakeholders working together towards the delisting of the California tiger salamander, and questioned why those efforts have stopped.

Our Response: A species may be downlisted or delisted if a review of its status shows that it has either recovered to the point it is no longer threatened or endangered, or if the threats to its survival and recovery have been reduced to the extent that the species is no longer threatened or endangered. These downlisting or delisting criteria are usually established in a recovery plan; however, decisions on downlisting and delisting may be made based upon a review of current scientific evidence. Completing a recovery plan for the California tiger salamander in Santa Barbara County and rangewide is important to us. Efforts on the Santa Barbara County portion of the range have helped us determine which areas are essential to the conservation of the California tiger salamander addressed herein. We are currently discussing how to proceed most efficiently and effectively with recovery planning efforts in light of our August 4, 2004, determination listing California tiger salamander rangewide as threatened (69 FR 47212).

Comment (77): One commenter stated that the certification of SBREFA has no analysis and is not supported.

Our Response: As required under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), when we published the proposed critical habitat rule, we included an assessment of the proposed rule's effects under SBREFA and certified the rule would not have a significant effect on a substantial number of small entities. We subsequently prepared and made available for public comment a draft economic analysis that describes the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). Please refer to the *Required*

Determinations section contained in this final rule for more information.

Comment (78): One commenter stated that the Service has failed to operate within the Administrative Procedure Act (APA), because its ''collaborative'' approach (*i.e.*, the recovery team) violates APA.

Our Response: We have been working with a recovery team on a draft recovery plan for the California tiger salamander in Santa Barbara County. We have used some of the information gathered for the draft recovery plan in helping us determine areas essential to the conservation of the California tiger salamander addressed herein. We did not hold meetings with the recovery team or otherwise ask the recovery team to help identify critical habitat units. Our efforts in this process fully comply with the ESA, and the APA.

Comment (79): One commenter asked how CEQA will, or how it is supposed to, review critical habitat designations. The commenter stated that critical habitat will prevent development without just cause.

Our Response: The CEQA guidelines state that a project would have a significant effect on the environment (meaning the potential need to prepare an Environmental Impact Report) if it would substantially affect a rare or endangered species or its habitat. In the case of California tiger salamander in Santa Barbara County, all of the critical habitat is occupied. Therefore, the critical habitat designation will not result in additional CEQA review solely on that basis.

All Federal agencies must consult under section 7 of the Act with us to ensure that any action that they authorize, fund, or carry out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat. Project proposals have been subject to our review process since the California tiger salamander was listed in 2000 (65 FR 57242). We have provided our best assessment of what the effects of the section 7 consultation requirement may be for private landowners as well as for State agencies proposing activities with a Federal nexus within designated critical habitat. The commenter provides no factual support for the assertion that designation of critical habitat will prevent development.

Comment (80): Several commenters stated that a Recovery Plan should be completed before critical habitat is designated.

Our Response: Section 4 of the Act requires us to designate critical habitat at the time of listing to the maximum extent prudent and determinable. In addition, we are under a court ordered deadline to complete critical habitat for the California tiger salamander in Santa Barbara County by November 15, 2004. While we agree that a recovery plan is a useful tool to assist us with determining which areas are essential for the conservation of a species, we are not at the liberty to postpone the final designation pending completion of a recovery plan. However, we have been working with a recovery team on a draft recovery plan for the California tiger salamander in Santa Barbara County and have used some of the information gathered for the draft recovery plan in helping us determine areas meeting the definition of critical habitat for the California tiger salamander addressed herein.

Comment (81): Two commenters stated their concerns regarding the short timelines the Service has to prepare rules such as this critical habitat designation. The commenters stated that shortened time frames force the Service to work with fewer facts.

Our Response: When we designate critical habitat at the time of listing or under short, court-ordered deadlines, we will often not have sufficient information to identify all areas of critical habitat. Nevertheless, we are required to make a decision and, thus, must base our designations on what, at the time of designation, we know to be critical habitat. In determining such areas, we used the best scientific and commercial data available, including information gathered by the science subteam of the recovery team for the CTS in Santa Barbara County (Service files 2002–2003).

Comment (82): One commenter stated that their property is not located within the mapped areas but they have still been told that they need to hire biologists to assess the site for potential California tiger salamanders and their habitat.

Our Response: California tiger salamanders could potentially occur throughout their range in northern Santa Barbara County. Most of the land is privately-owned and has not been surveyed. Surveys following specified protocols (available from the Ventura Fish and Wildlife Office) are recommended to assess the likelihood that California tiger salamanders are present on a particular property. Property with suitable habitat (aquatic or upland) within the range of the California tiger salamander may harbor California tiger salamanders. If so, any activities involving ground disturbance could result in take. Protocol surveys provide a useful tool to establish that California tiger salamanders are unlikely to be present on a specific property.

Comment (83): A few commenters asked why, if critical habitat adds little protection to a listed species as stated in the language in the beginning of each critical habitat rule, then why does the Service continue to designate critical habitat?

Our Response: Section 4 of the Endangered Species Act of 1973, as amended, and our implementing regulations, state that critical habitat shall be designated for species listed under the Act unless the Secretary determines that such designation is not prudent or not determinable.

Comment (84): One commenter stated that the designation specifies the need for more ponds to be built and upland habitat to be restored and asked who would do this, as most of the critical habitat occurs on private land.

Our Response: The measures mentioned in the proposed rule refer to recommendations made by the science subteam of the recovery team for the CTS in Santa Barbara County to enhance and protect California tiger salamander habitat (Service files 2002–2003). Critical habitat designations affect only activities that require Federal permits or funding, and do not require landowners to carry out special management or restrict use of their land. We have been, and will continue, to work with interested individuals, organizations, and agencies on a voluntary basis to implement conservation and recovery actions that will benefit the California tiger salamander.

Comment (85): One commenter stated that the County of Santa Barbara incorporates critical habitat designations, such as the one for the California tiger salamander into their own regulations, which they then enforce.

Our Response: We do not dictate how a local government, such as Santa Barbara County, uses critical habitat designations. However, from the point of view of the Federal government, a critical habitat designation does not allow either government or public access to private land, and similarly will not result in the closure of the area to access or use. If a species is listed or critical habitat is designated, section 7(a)(2) requires Federal agencies to insure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat.

Summary of Changes From the Proposed Rule

In preparing our final designation of critical habitat for the California tiger salamander, we reviewed comments received on the proposed designation of critical habitat. In addition to minor clarifications in the text pertaining to State and Federal projects and section 7 consultations (see State comment (4)), we made five changes to our proposed designation, as follows:

(1) We made revisions to preamble based on information supplied by commenters which clarified the U.S. Federal Highway Administration's oversight during section 7 consultations.

(2) Under section 4(b)(2) of the Act, we excluded properties with adequate management plans that cover the California tiger salamander and its habitat. For more information, refer to *Exclusions Under Section 4(b)(2) of the Act* below.

(3) We excluded an existing vineyard from critical habitat Unit 6 (Santa Rita Valley) that was included in the proposed rule as a result of a mapping error.

(4) Based on comments on the proposed rule, we found that the generalized boundaries we employed were too inaccurate. Therefore, the final critical habitat boundaries were refined to more closely follow actual landscape features (such as roads) that can be more readily found on the ground. For example, the proposed critical habitat Unit 1, Western Santa Maria, showed the boundary extending slightly south of State Highway 1. The boundary for the final critical habitat for Unit 1 stays north of State Highway 1.

(5) Collectively, we excluded a total of 2,740 ac (1,109 ha) of privately-owned lands from this final critical habitat designation.

TABLE 1.—PROPOSED AND FINAL CRITICAL HABITAT ACREAGES

Unit	Proposed/final acreage	
1. Western Santa Maria/Orcutt	4,349 ac (1,760 ha)	4,135 ac (1,673 ha)
2. Eastern Santa Maria	2,985 ac (1,208 ha)	2,909 ac (1,177 ha)
3. Western Los Alamos/Careaga	2,181 ac (882 ha)	1,451 ac (587 ha)
4. Eastern Los Alamos	1,302 ac (527 ha)	90 ac (36 ha)
5. Purisima Hills	2,359 ac (955 ha)	1,957 ac (792 ha)
6. Santa Rita Valley	744 ac (301 ha)	638 ac (258 ha)
Total	13,920 ac (5,633 ha)	11,180 ac (4,523 ha)

Critical Habitat

Critical habitat is defined in section 3 of the Act as—(i) the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species, and (II) that may require special management considerations or protection; and, (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. ''Conservation,'' as defined by the Act, means the use of all methods and procedures that are necessary to bring an endangered or a threatened species to the point at which listing under the Act is no longer necessary.

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification of critical habitat with regard to actions carried out, funded, or authorized by a Federal agency. Section 7 also requires conferences on Federal actions that are likely to result in the destruction or adverse modification of proposed critical habitat.

To be included in a critical habitat designation, the habitat must contain the physical and biological features ''essential to the conservation of the species.'' Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species (*i.e.*, areas on which are found the primary constituent elements, as defined at 50 CFR 424.12(b)).

Our Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (59 FR 34271), and our U.S. Fish and Wildlife Service Information Quality Guidelines (2002) provide criteria, establish procedures, and provide guidance to ensure that our decisions represent the best scientific and commercial data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, or other unpublished materials and expert opinion or personal knowledge.

Critical habitat designations do not signal that habitat outside the designation is unimportant to the California tiger salamander in Santa Barbara County. Areas outside the critical habitat designation will continue to be subject to conservation actions that may be implemented under section 7(a)(1), and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the section 9 take prohibition, as determined on the basis of the best available information at the time of the action. We specifically anticipate that federally funded or assisted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Methods

Our methods for identifying the California tiger salamander critical habitat included in this final designation are identical to the methods we used in our proposal of critical habitat for the California tiger salamander, published on January 22, 2004 (69 FR 3064).

On August 10, 2004, we proposed critical habitat for the California tiger salamander, Central population, in four

regions: Central Valley, Southern San Joaquin Valley, East Bay, and Central Coast (69 FR 48570). The methods used to identify critical habitat in the Central designation are similar in nature to the methods used for the critical habitat designation for the CTS in Santa Barbara County; some methods differ as a result of differences in local biological and commercial data for each population. For example, the proposed designation for the California tiger salamander, Central population, includes an additional primary constituent element as a result of habitat features specific to that population (69 FR 48575).

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining what areas are critical habitat, we shall consider those physical and biological features that are essential to the conservation of the species and, within areas currently occupied by the species, that may require special management considerations or protection. These generally include, but are not limited to, the following: Space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, and rearing (or development) of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species. Further, when considering the designation of critical habitat, we shall focus on the principal biological or physical constituent elements (*i.e.*, PCEs) within the defined area that are essential to the conservation of the species.

The specific PCEs required for California tiger salamander critical habitat are derived from the biological needs of the California tiger salamander as described below.

The areas proposed for designation as critical habitat for the California tiger salamander are designed to provide sufficient aquatic habitat for breeding and upland habitat as refugia for adults to maintain and sustain populations of California tiger salamanders throughout their range, and provide those habitat components essential for the conservation of the species. Due to the complex life history and dispersal capabilities of California tiger salamanders, and the dynamic nature of the environments in which they are found, the primary constituent elements described below should be found throughout the units that are being designated as critical habitat. Critical habitat for California tiger salamanders will provide for breeding and nonbreeding habitat and for dispersal between these habitats, as well as allowing for an increase in the size of California tiger salamander populations, which is essential to the conservation of the subspecies.

Critical habitat includes: Essential aquatic habitat, essential upland nonbreeding season habitat with underground refugia, and dispersal habitat connecting occupied California tiger salamander locations to each other. Based on our current knowledge of the life history and ecology of the species and the relationship of its essential life history functions to its habitat, as summarized in the *Background* section of the proposed critical habitat rule (69 FR 3064), we have determined that the California tiger salamander requires the following primary constituent elements: (1) Standing bodies of fresh water, including natural and man-made (*e.g.*, stock) ponds, vernal pools, and dune ponds, and other ephemeral or permanent water bodies that typically become inundated during winter rains and hold water for a sufficient length of time (*i.e.*, 12 weeks) necessary for the species to complete the aquatic portion of its life cycle. (2) Barrier-free uplands adjacent to breeding ponds that contain small mammal burrows. Small mammals are essential in creating the underground habitat that adult California tiger salamanders depend upon for food, shelter, and protection from the elements and predation. (3) Upland areas between breeding locations (PCE 1) and areas with small mammal burrows (PCE 2) that allow for dispersal among such sites.

We describe the relationship between each of these PCEs and the conservation of the salamander in more detail below. The essential aquatic habitat described as the first PCE is essential for California tiger salamander breeding and for providing space, food, and cover necessary to sustain early life history stages of California tiger salamanders. Breeding habitat consists of fresh water bodies, including natural and man-made (*e.g.*, stock) ponds, vernal pools, and dune ponds. To be considered essential, aquatic habitats must have the potential to hold water for a minimum of 12 weeks in the winter or spring in a year of average rainfall because this is the amount of time needed for juveniles to complete metamorphosis and become capable of surviving in upland habitats. During periods of drought or less-than average rainfall, these breeding sites may not hold water long enough for individuals to complete metamorphosis, but these sites would still be considered essential because they constitute breeding habitat in years of average rainfall. Without its essential aquatic habitat, the California tiger salamander would not survive, because no breeding could occur.

Associated upland habitat containing underground refugia described as the second PCE is essential for the survival of adult California tiger salamanders and juveniles that have recently undergone metamorphosis. Adult and juvenile California tiger salamanders are terrestrial, and they enter aquatic habitats only for short periods of time to breed. For the majority of their life cycle, California tiger salamanders depend for survival on upland habitats containing underground refugia in the form of small mammal burrows. These underground refugia provide protection from the hot, dry weather typical of Santa Barbara County in the nonbreeding season. California tiger salamanders also find food in small mammal burrows and rely on the burrows for protection from predators. The dispersal habitat described as the third PCE is essential for the conservation of the California tiger salamander. Protecting the ability of California tiger salamanders to move freely across the landscape in search of breeding ponds is essential in maintaining gene flow and for recolonization of sites that are temporarily extirpated.

Lifetime reproductive success for California and other tiger salamanders is low. Trenham *et al.* (2000) found the average female bred 1.4 times and produced 8.5 young that survived to metamorphosis per reproductive effort. This resulted in roughly 11 metamorphic offspring over the lifetime of a female. In part, this low reproductive success is due to the extended time it takes for California tiger salamanders to reach sexual maturity: Most do not breed until 4 or 5 years of age. While individuals may survive for more than 10 years, many breed only once. Combined with low survivorship of metamorphosed individuals (in some populations, less than 5 percent of marked juveniles survive to become breeding adults (Trenham *et al.* 2000)), reproductive output in most years is not sufficient to maintain populations. This trend suggests that the species requires occasional ''boom'' breeding events to prevent extirpation (temporary or permanent loss of the species from a particular habitat) or extinction (Trenham *et al.* 2000).

With such low recruitment, isolated populations are susceptible to unusual, randomly occurring natural events as

well as from human-caused factors that reduce breeding success and individual survival. Factors that repeatedly lower breeding success in isolated pools can quickly extirpate a population. Therefore, a critical element for successful conservation is the maintenance of sets of interconnected sites that are within the ''rescue'' distance of other ponds (Trenham *et al.* 2001). Dispersal habitat described as the third PCE is also essential in preserving the California tiger salamander's population structure. The life history and ecology of the California tiger salamander make it likely that this species has a metapopulation structure (Hanski and Gilpin 1991). A metapopulation is a set of local populations or breeding sites within an area, where typically migration from one local population or breeding site to other areas containing suitable habitat is possible, but not routine. Movement between areas containing suitable habitat (*i.e.*, dispersal) is restricted due to inhospitable conditions around and between areas of suitable habitat. Because many of the areas of suitable habitat may be small and support small numbers of salamanders, local extinction of these small units may be common.

A metapopulation's persistence depends on the combined dynamics of these local extinctions and the subsequent recolonization of these areas through dispersal (Hanski and Gilpin 1991; Hanski 1994). Essential dispersal habitat generally consists of upland areas adjacent to essential aquatic habitat that are not isolated from breeding ponds by barriers that California tiger salamanders cannot cross. Essential dispersal habitat provides connectivity among California tiger salamander breeding ponds. While California tiger salamanders can bypass many obstacles, and do not require a particular type of habitat for dispersal, the habitat connecting essential aquatic habitat must be free of barriers (*e.g.*, a physical or biological feature that prevents salamanders from dispersing beyond the feature). Examples of barriers are areas of steep topography devoid of soil or vegetation and State Highway 101. Agricultural lands such as row crops, orchards, vineyards, and pastures do not constitute barriers to the dispersal of California tiger salamanders.

In general, we are designating critical habitat that allows for dispersal between breeding locations within 0.70 mi (1,158 m) of each other; however, we decreased or increased this distance based on site-specific conditions within each unit. In summary, the primary constituent elements consist of three components. At a minimum, this will include suitable breeding locations and associated uplands surrounding these water bodies that are connected by dispersal habitat that is free of barriers.

Criteria Used To Identify Critical Habitat

To identify areas that are essential to the conservation of the California tiger salamander in Santa Barbara County, we first looked at the potential range of the species in Santa Barbara County, as mapped in spring of 2000 by biologists who had conducted California tiger salamander surveys throughout Santa Barbara County. The boundaries of the potential range were developed based on topography, geology, and survey information. In some areas (*e.g.*, Vandenberg Air Force Base), seemingly appropriate habitat was excluded based on several years of negative survey results. Other areas (*e.g.*, the Solomon Hills) had slopes too steep to support ponding necessary for California tiger salamander breeding. Other areas of intact habitat adjacent to known ponds were included, and areas with extensive ponded wetland habitat (*e.g.*, Guadalupe Lakes) were also included.

We then focused on areas within the range where we had credible records (*e.g.*, museum voucher specimens, reports filed by biologists holding section 10(a)(1)(A) recovery permits) indicating California tiger salamander presence. The known locations of California tiger salamanders fall into six disparate areas of Santa Barbara County. Our conservation strategy focuses on providing sufficient breeding and upland habitat to ensure high enough adult survival to maintain and sustain existing populations of California tiger salamanders in each of these six areas within the County. Each of the six areas has a distinctive combination of habitat types, breeding pond types, landscape features, surrounding land uses, and topography. Because of the population size, and the existing threats, we determined that conservation of each of these six populations and the habitats essential to support them is essential to the conservation of the California tiger salamander in Santa Barbara County and to the species as a whole.

Conserving California tiger salamanders over the long term requires a three-pronged approach: (1) Protecting the hydrology and water quality of breeding pools and ponds; (2) retaining or providing for connectivity between breeding locations for genetic exchange and recolonization; and (3) protecting sufficient upland habitat around each breeding location to allow for high enough adult survival to maintain a breeding population over the long term. An explanation of how we determined the amount of upland habitat that is essential for the conservation of the California tiger salamander in each critical habitat unit is described in more detail below.

Once we identified the known breeding locations, we mapped the upland watershed of each pond based on aerial photographs taken in 2002 (AirPhotoUSA Inc. 2002) overlain with topographic relief lines. Protecting the watersheds of breeding ponds is essential for two reasons: (1) To ensure that the amount of water entering the pond is not altered in a manner that would allow for colonization of breeding sites by bullfrogs and fish, which can prey upon California tiger salamander eggs and larvae and (2) to preserve water quality by minimizing the entry of sediments and other contaminants to the breeding ponds. Therefore, our critical habitat boundaries include the watersheds of all known breeding ponds.

We then identified the upland habitat surrounding the ponds where juvenile and adult California tiger salamanders live during the majority of their life cycle. To determine a general guideline for the amount of upland habitat necessary to support a population of adult California tiger salamanders, we reviewed the primary literature regarding California tiger salamander upland habitat use, including Trenham (2001), Trenham *et al.* (2000), and Trenham and Shaffer (unpublished manuscript). We also reviewed information from other biologists who have conducted upland habitat use studies but have not yet written up the results (*e.g.*, Sue Orloff, Steve Sykes, SAIC—see *Background* section of the proposed critical habitat rule (69 FR 3064)).

Data indicate that California tiger salamanders do not remain primarily in burrows close to breeding ponds, but instead move some distance out into the surrounding landscape. As described in the Background section of the proposed critical habitat rule (69 FR 3064), California tiger salamanders have been found up to 1.2 mi (2 kms) from breeding ponds. However, most California tiger salamanders are found closer to the ponds. Two studies conducted in Monterey and Solano Counties provide the best available data on upland movement distances. First, the mark-recapture study of Trenham *et al.* (2001) showed that California tiger salamanders commonly moved between ponds separated by 2,200 ft (671 m), suggesting that movements of this

magnitude are not rare. Second, the ongoing study at Olcott Lake (Solano County) has directly documented the presence of high densities of juvenile and adult California tiger salamanders at upland locations at least 1,312 ft (400 m) from this breeding pond. Recent trapping efforts captured large numbers (representing 16 percent of total captures) of juvenile salamanders at 2,296 ft (700 m) (Trenham *et al.* unpublished data). Trenham and Shaffer (unpublished manuscript) determined that conserving upland habitats within 2,200 ft (671 m) of breeding ponds would protect 95 percent of California tiger salamanders at their study location in Solano County. Based on this information, we focused on protecting upland areas within 2,200 ft (671 m) of a known breeding pond. Protecting an upland habitat area with a radius of 2,200 ft (671 m) around a single pond yields a minimum area of 350 ac (145 ha), but depending on the size of the pond, can be more than that.

We used 2,200 ft (671 m) or 350 ac (145 ha) as a guide for the amount of upland habitat around known breeding locations to be mapped as critical habitat for the purposes of preserving California tiger salamanders within small mammal burrows (PCE 2). However, although the studies discussed above provide an approximation of the distances that California tiger salamanders can move from their breeding ponds in search of suitable upland refugia, we recognize that upland habitat features will influence California tiger salamander movements in a particular landscape. Therefore, where we had site-specific information on those features, such as land use, topography, and geologic landform, we altered critical habitat lines to reflect that information. In some locations, we protected a shorter distance than 2,200 ft (671 m) if: (1) Commercial or residential developed areas were present (*e.g.*, Santa Maria), (2) the upland habitat was separated from the breeding habitat by a substantial barrier (*e.g.*, State Highway 101); (3) the habitat type within that distance was unsuitable for California tiger salamanders (*e.g.*, hard chaparral); or (4) the area did not provide underground refugia because it could not support small mammal burrowing systems due to geological features such as fractured shales. We also excluded areas based on a combination of topography and geology. If soil and vegetative conditions are appropriate, California tiger salamanders can traverse areas of steep topography. Some steep areas do not support soils or vegetation that allow for California tiger salamanders to traverse. Therefore, we excluded areas that we know to be both steep and devoid of vegetation or burrowing mammal potential.

In some cases, we extended the boundary of critical habitat beyond 2,200 ft (671 m) if (1) suitable but unsurveyed breeding locations were present that would augment California tiger salamander populations; (2) no barriers to California tiger salamander dispersal are present and the habitat is suitable; (3) watershed boundaries for known breeding ponds exceed distances of 2,200 ft (671 m); or (4) the upland area between breeding ponds was conducive to California tiger salamander travel and would facilitate dispersal between ponds within the units which is essential for California tiger salamander gene flow.

We excluded most areas of frequently harvested agricultural lands from the boundaries of critical habitat areas. Agricultural lands were only included if they are directly adjacent to known breeding ponds, thereby providing the only available upland refugia for California tiger salamanders breeding in that pond, or providing essential connectivity between known breeding locations. In the case of the two units within the Santa Maria Valley, so little California tiger salamander good quality upland refugia habitat is left that restoration is necessary to provide sufficient good quality upland refugia to sustain a population of adult California tiger salamanders. Currently, the majority of habitat within these two units provide for dispersal purposes (*i.e.*, they provide connectivity between aquatic and upland habitats).

To determine the areas to be mapped within each unit for the purposes of dispersal (*i.e.* PCE 3), we used a distance of 0.70 mi (1.1 km) as a general guide. The only known study we are aware of that specifically investigated movement of California tiger salamanders between breeding ponds projected that 0.70 mi (1.1 km) would encompass 99 percent of interpond dispersal (Trenham *et al.* 2001; Trenham pers. comm. 2004) However, we recognize that (as with movements in search of suitable underground refugia) upland habitat features influence California tiger salamander movements within a particular landscape. Thus, we altered critical habitat unit boundaries to reflect site-specific knowledge where it was available to us. In some units, we protected a shorter dispersal distance than 0.70 mi (1.1 km) for similar reasons as described for PCE 2 (*e.g.* barriers prevented movement, no ponds existed in a given direction).

In one unit (the eastern Santa Maria Unit) we included a dispersal corridor of 1.2 mi, which extends a greater distance than 0.70 mi (1.1 km) between breeding locations. In general, we designated critical habitat that allows for dispersal between breeding locations within 0.70 mi (1,158 m) of each other; however, we decreased or increased this distance based on site-specific conditions within each unit. We determined the longer corridor within this unit was justified given the observations by S. Sweet (in litt. 1998), where he found an adult California tiger salamander 1.2 mi (1.9 km) from the closest breeding location within this unit, and because of the relatively flat, barrier-free terrain between the breeding locations. We determined that the connection between the two known breeding areas is essential for the conservation of the California tiger salamander in this area, because, without it, these locations would become isolated and much more susceptible to extirpation.

We are designating critical habitat on lands that contain the physical or biological features considered essential to the conservation of the California tiger salamander (see *Primary Constituent Elements* section).

All of the known locations for the California tiger salamander in Santa Barbara County occur on non-Federal and private lands. Section 10(a)(1)(B) of the Act authorizes us to issue permits for the take of listed species incidental to otherwise lawful activities. An incidental take permit application must be supported by a habitat conservation plan (HCP) that identifies conservation measures that the permittee agrees to implement for the species to minimize and mitigate the impacts of the requested incidental take. We often exclude non-Federal public lands and private lands that are covered by an existing operative HCP and executed implementation agreement (IA) under section 10(a)(1)(B) of the Act from designated critical habitat because the benefits of exclusion outweigh the benefits of inclusion as discussed in section 4(b)(2) of the Act. In the case of the California tiger salamander, no lands are covered by an existing operative HCP. We are aware of three HCPs under development; however, we have not excluded these draft HCPs because we have not yet made an initial determination that they meet our issuance criteria and are ready for public notice and comment.

When defining critical habitat boundaries, we made an effort to exclude all developed areas, such as towns, housing developments, and other

lands unlikely to contain PCEs essential for California tiger salamander conservation. However, our minimum mapping unit does not exclude all developed lands, such as lands supporting outbuildings, paddocks, roads, ROWs, paved areas, and lawns that do not contain PCEs. These areas are not included in the designation. These areas have been excluded by text and Federal actions limited to these areas would not trigger a section 7 consultation, unless they affect the species and/or the PCEs in adjacent critical habitat.

In summary, we designate six areas where populations of California tiger salamander are known to occur as critical habitat because the primary constituent elements need protection and/or special management to ensure any change to existing management does not adversely modify the critical habitat and protection of those areas is essential to the conservation of the species. We then mapped as critical habitat sufficient habitat to ensure the conservation of the California tiger salamander.

Special Management Considerations or Protections

When designating critical habitat, we assess whether the areas determined to be essential for conservation may require special management considerations or protections. Areas in need of management for the California tiger salamander include not only the immediate locations where the species may be present at a particular point in time, but additional areas adjacent to these that are essential to provide for normal population fluctuations that may occur in response to natural and unpredictable events. The California tiger salamander are dependent upon habitat components beyond the immediate areas where individuals of the species occur at any given time, because these areas are important in maintaining ecological processes such as hydrology, expansion of distribution, recolonization, and maintenance of natural predator-prey relationships, all of which are essential for the conservation of the species.

We believe that the areas proposed for critical habitat may require special management considerations or protections due to the threats outlined below:

(1) Non-native and introduced predators such as bullfrogs and fish.

(2) Disturbance of aquatic breeding habitats during the breeding season.

(3) Sedimentation and erosion into water bodies.

(4) Contamination by chemicals such as those used for agricultural purposes.

(5) Habitat loss due to construction of barriers or elimination of small mammal burrows.

Relationship to Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that critical habitat shall be designated, and revised, on the basis of the best available scientific data after taking into consideration the economic impact, the effect on national security, and any other relevant impact, of specifying any particular area as critical habitat. An area may be excluded from critical habitat if it is determined, following an analysis, that the benefits of such exclusion outweigh the benefits of specifying a particular area as critical habitat, unless the failure to designate such area as critical habitat will result in the extinction of the species. Consequently, we may exclude an area from designated critical habitat based on economic impacts, the effect on national security, or other relevant impacts such as preservation of conservation partnerships, if we determine the benefits of excluding an area from critical habitat outweigh the benefits of including the area in critical habitat, provided the action of excluding the area will not result in the extinction of the species.

In our critical habitat designations, we have used the provisions outlined in section 4(b)(2) of the Act to evaluate those specific areas that are proposed for designation as critical habitat and those areas that are subsequently finalized (*i.e.*, designated). We have applied the provisions of this section of the Act to land meeting the definition of critical habitat of the subject species to evaluate excluding them from critical habitat. Lands that we have either excluded from or not included in critical habitat based on those provisions include those covered by: (1) Legally operative Habitat Conservation Plans (HCPs) that cover the species, and provide assurances that the conservation measures for the species will be implemented and effective; (2) draft HCPs that cover the species, have undergone public review and comment, and provide assurances that the conservation measures for the species will be implemented and effective (*i.e.*, pending HCPs); (3) Tribal conservation plans that cover the species and provide assurances that the conservation measures for the species will be implemented and effective; (4) State conservation plans that provide assurances that the conservation measures for the species will be implemented and effective; (5) Fish and Wildlife Service Comprehensive Conservation Plans that provide assurances that the conservation measures for the species will be implemented and effective; and (6) adequate management plans or agreements that protect the primary constituent elements of the habitat.

Critical Habitat Designation

We are designating six units as critical habitat for the California tiger salamander. The critical habitat areas described below constitute our best assessment at this time of the areas essential for the conservation of the California tiger salamander. The six areas designated as critical habitat are: (1) Western Santa Maria/Orcutt; (2) eastern Santa Maria; (3) western Los Alamos/Careaga; (4) eastern Los Alamos; (5) Purisima Hills; and (6) Santa Rita Valley.

The approximate area encompassed within each critical habitat unit is shown in Table 2.

TABLE 2.—FINAL CRITICAL HABITAT UNITS FOR THE CALIFORNIA TIGER SALAMANDER IN SANTA BARBARA COUNTY

Critical habitat unit	Acres	Hectares
1. Western Santa Maria/Orcutt	4,135	1,673
2. Eastern Santa Maria	2,909	1,177
3. Western Los Alamos/Careaga	1,451	587
4. Eastern Los Alamos	90	36
5. Purisima Hills	1,957	792
6. Santa Rita Valley	638	258
Total	11,180	4,523

The majority of the acreage occurs on privately owned land. We know of no Federal, State, tribal, or military lands within these boundaries. A small portion of land within the western Santa Maria/Orcutt Unit is owned by local jurisdictions, including the county of Santa Barbara and the Laguna County Sanitation District.

Critical habitat includes California tiger salamander habitat throughout the species' range in Santa Barbara County, California. Brief descriptions of all units, and reasons why they are essential for the conservation of the California tiger salamander, are presented below. Each unit contains essential aquatic, upland, and dispersal habitat. Each unit is occupied by California tiger salamanders based upon observations recorded since 2000.

Unit 1: Western Santa Maria/Orcutt

Modifications were made to this unit as a result of a revised mapping methodology, which resulted in more accurately showing the boundary of this unit. This modification resulted in the reduction from 4,349 ac (1,760 ha) to 4,135 ac (1,673 ha).

Unit 1 consists of 4,135 ac (1,673 ha) west and southwest of the city of Santa Maria, mostly in unincorporated areas of the County and the community of Orcutt. This area encompasses the known California tiger salamander breeding sites extending from the Casmalia Hills on the south to the Santa Maria Airport on the north and from west of Black Road eastward to Highway 135. This unit makes up 26 percent of the total area we have identified as containing the PCEs for the species and as being essential to the conservation of the species in Santa Barbara County. The unit contains 12 known California tiger salamander breeding ponds and several water bodies that are suitable for breeding California tiger salamanders but that have never been surveyed. The 12 known breeding ponds in this unit constitute approximately 26 percent of the known breeding ponds (46) in Santa Barbara County.

Of even greater significance, Unit 1 contains 7 (approximately 37 percent) of the 19 natural vernal ponds that occur in Santa Barbara County. These natural ponds occur on the Orcutt Dune Sheet, which contains soils that are unique to the Santa Maria Valley. The Orcutt Dune Sheet is an ancient, windblown sand deposit that covers the southern one-half to two-thirds of the Santa Maria Valley (Hunt 1993). All natural California tiger salamander breeding sites occurring on the sheet are classified as dunal or deflation pools and ponds, a type of California tiger salamander breeding pond occurring only within the two units within the Santa Maria Valley. The five remaining known ponds occur along the base of the Casmalia Hills, just off the southwestern edge of the Orcutt Dune Sheet.

Population growth and the concomitant residential and commercial development are the greatest threat to California tiger salamanders within this unit. The city of Santa Maria currently sustains a population of 82,148 people and is anticipated to reach a population of 110,800 people by 2020, with an annual growth rate of 1.8 percent (Santa Barbara County Association of Governments 2002). Annexations to further development are proposed in the remaining California tiger salamander habitat (Marc Bierdzinski, Santa Maria Community Development Department, pers. comm. 2003).

The city of Santa Maria is the fastest growing city in Santa Barbara County, with a 26 percent increase in population in the 1990s (16,000 new residents). Santa Barbara County's population is projected to grow by at least 160,000 people in the next 30 years (Santa Barbara County Planning and Development 2002). Depending on housing densities, the county may need over 15,000 ac (6,070 ha) of residentially zoned land on which to build homes to meet this goal (Santa Barbara County Planning and Development 2002). All of the urban areas in the county except Santa Maria and Orcutt have nearly exhausted land zoned for residential development. The California Department of Housing and Community Development expects the county and cities to set aside land for over 17,500 homes in the next seven years (Santa Barbara County Planning and Development 2002). Approximately 3,600 ac (1,457 ha) of prime agricultural land has been annexed to meet the increase in population. Prime farmland east and west of Santa Maria currently designated by the City of Santa Maria as ''No Urban Development Areas'' are expected to face increasing pressure to develop as the city exhausts land available for development around 2010 (Santa Barbara County Planning and Development 2002).

Several development projects have been proposed within Unit 1. The Santa Maria Airport District proposes to build a 400-ac (162-ha) research park and golf course just south of the airport on a parcel with three known California tiger salamander breeding ponds (Rincon 2002). The Orcutt Community Plan identifies Key Site 22 as a site for 60 percent buildout to a maximum of 3,000 units of dwellings (Santa Barbara County 2002). This site lies entirely within the critical habitat unit. Additional proposed development projects include Union Valley Parkway (City of Santa Maria 2003) and expansion of the Laguna County Sanitation District's wastewater treatment plan.

In the West Santa Maria subpopulation, 78 percent of California tiger salamander upland habitat has been lost or separated from breeding ponds by fragmentation. Three large development projects (Mahoney Ranch, Key Site 22, and the Santa Maria Airport Research Park and Golf Course) threaten most of the remaining habitat. The Santa Maria Airport has worked with the Service to develop a plan that will minimize impacts to the California tiger salamander; however, one of the most productive ponds, the easternmost pond on the Santa Maria Airport property, will be permanently isolated from all other ponds on a 120-acre (49-ha) reserve once the Santa Maria Airport Research Park goes forward (Service files). A number of smaller development projects (Laguna Sanitation District Expansion, construction of three administrative buildings on Foster Road, Union Valley Parkway) also threaten to further reduce the available upland habitat and fragment the breeding ponds from each other.

This unit is essential to the conservation of the California tiger salamander because it contains 37 percent of the natural vernal pools for this Santa Barbara population. It is critical for the conservation of the species to conserve the California tiger salamander within a range of habitat types as protecting a variety of habitat conditions will increase the ability of the species to survive stochastic events.

This unit requires special management to continue efforts to protect PCEs essential for the conservation of California tiger salamanders. In particular, one pond is known to have introduced fish, another is subject to berm failure, and bullfrogs breed in close proximity to a third site. Managing these ponds to maintain the existing PCEs is essential for the conservation of the California tiger salamander. Addressing the removal of upland habitat (PCE 2) and dispersal habitat (PCE 3) due to building pressures through special management or protection is essential for the conservation of the California tiger salamander.

Unit 2: Eastern Santa Maria

Modifications were made to this unit as a result of a revised mapping methodology, which resulted in more

accurately showing the boundary of this unit. This modification resulted in the reduction from 2,985 ac (1,208 ha) to 2,909 ac (1,177 ha).

This unit covers a portion of the eastern half of the Orcutt Dune Sheet, but is separated from the western Santa Maria Valley unit by a broad area of urban and agricultural development, including State Highways 135 and 101. The unit is 2,909 ac (1,177 ha) in size and is bordered by State Highway 101 on the west, the Solomon Hills on the south, the Sisquoc River on the east, and the Santa Maria River floodplain on the north. This unit makes up 26 percent of the total area we have identified as containing the PCEs for the species and as being essential to the conservation of the species in Santa Barbara County. The unit contains 4 known California tiger salamander breeding ponds and additional water bodies that are suitable for breeding California tiger salamanders but that have never been surveyed.

The four known breeding ponds in Unit 2 are natural vernal pools. Therefore, Unit 2 represents approximately 21 percent of the natural vernal pools used for California tiger salamander breeding in Santa Barbara County (19 natural vernal ponds total). The four of the known breeding ponds in Unit 2 have had substantial alterations to the surrounding upland habitats, and substantial fragmentation of the habitat between breeding ponds has occurred.

This unit contains primary constituent elements essential to the conservation of the California tiger salamander in Santa Barbara County because it contains 21 percent of the natural vernal pools (PCE 1) in the Santa Barbara County population. It is critical for the conservation of the species to conserve the California tiger salamander within a range of habitat types as protecting a variety of habitat conditions will increase the ability of the species to survive stochastic events. At least 10 additional ponds that appear suitable for California tiger salamander breeding exist within the unit.

As mentioned in the discussion under Unit 1, the Santa Maria Valley is quickly growing, and both Unit 1 and Unit 2 are facing increasing pressure due to development. Some proposed projects further threaten the remaining California tiger salamander habitat, including the 2000-ac (809-ha) Bradley Ranch proposed development project (John L. Wallace & Associates 2002), scattered low-density residential development, two soil remediation projects, and the construction of a radio tower. Additionally, Unit 2 has also experienced some loss of California tiger salamander habitat due to illegally-conducted ground disturbing activities.

Unit 3: Western Los Alamos/Careaga

Part of this unit was excluded from this final critical habitat designation because this area is actively managed for the protection and enhancement of California tiger salamander habitat (refer to *Exclusions Under Section 4(b)(2) of the Act*). This modification resulted in the reduction from 2,181 ac (882 ha) to 1,451 ac (587 ha).

This unit consists of 1,451 ac (587 ha) to the west of Highway 101, bordered on the west by the Careaga Divide. Four ponds within this unit have been documented as breeding habitat by California tiger salamanders. Several other agricultural impoundments are located within dispersal distance of the California tiger salamander breeding ponds in the western Los Alamos Valley. These human-made ponds may also be used by California tiger salamanders for breeding.

In contrast to the dunal or deflation ponds found in the two units to the north within the Santa Maria Valley, the natural breeding ponds within the Western Los Alamos/Careaga Unit are found in structural basin ponds. These ponds occur in the valleys or depressions along the axes of the synclines. The natural ponds within the unit occur along the axis of the Los Alamos Syncline and an unnamed syncline occurring parallel to and west of the Los Alamos Syncline.

This unit contains primary constituent elements essential to the conservation of the California tiger salamander because it contains some of the highest-quality natural California tiger salamander breeding pools remaining in the County. The Careaga Divide pond, located on the western side of the unit, is one of the most unique and pristine vernal ponds (PCE 1) where California tiger salamanders breed. The wetland is unique in that it is enclosed on two sides by extensive, dense coast live oak woodland, and by coastal sage scrub and grasslands. The unit also provides large blocks of continuous unfragmented upland habitat with few known sources of mortality, all occurring within a working rangeland landscape (PCE 2 and 3). The unit requires special management in the form of fish removal from at least one pond and sediment control at three ponds (PCE 1). This unit also requires protection and special management to reduce other threats, including berm failure and vineyard development proposals that could reduce aquatic, upland refugia and dispersal habitats (PCEs 1, 2 and 3). The current surrounding land use is cattle grazing.

Unit 4: Eastern Los Alamos

Part of this unit was excluded from this final critical habitat designation because this area is actively managed for the protection and enhancement of California tiger salamander habitat (refer to *Exclusions Under Section 4(b)(2) of the Act* section below). This modification resulted in the reduction from 1,302 ac (527 ha) to 90 ac (36 ha).

This unit consists of two separate parcels, one 27 ac (10.9 ha) parcel and one 63.7 ac (25.8 ha) parcel, for a total of 90 ac (36 ha). This unit is located south of Highway 101 and southeast of the town of Los Alamos. This population is currently comprised of four known California tiger salamander breeding ponds; however, the property on which these four ponds are located has been excluded from this designation due to a conservation strategy that the landowners have created to enhance existing and create additional California tiger salamander aquatic habitat.

Given the small number of known breeding populations, the acreage remaining in this final designation contains primary constituent elements essential for the conservation of the California tiger salamander, because, despite its location adjacent to State Highway 101, it provides essential upland habitat. In addition, the acreage remaining within this unit is essential to support a self-sustaining population of California tiger salamanders. Furthermore, the populations within this unit constitute the easternmost location of the species in Santa Barbara County. It is critical for the conservation of the species to conserve the California tiger salamander within the range of habitat types where it is found in nature. Protecting a variety of habitat conditions will increase the ability of the species to survive stochastic events.

The unit requires special management to address the threats of road mortality and upland habitat loss.

Unit 5: Purisima Hills

Part of this unit was excluded from this final critical habitat designation because this area is actively managed for the protection and enhancement of California tiger salamander habitat (refer to *Exclusions Under Section 4(b)(2) of the Act* section). This modification resulted in the reduction from 2,359 ac (955 ha) to 1,957 ac (792 ha).

Unit 5 consists of 1,957 ac (792 ha) along the crest and south slope of the west-central portion of the Purisima Hills. The unit encompasses 14 of the 16

documented breeding ponds in the subpopulation. The portion of the Purisima Hills that contains suitable habitat lies upon the lower Careaga Formation, bounded to the east-southeast by outcrops of Sisquoc Formation, and bounded to the west-northwest by badlands topography of sandier horizons within the upper Careaga Formation. Neither the Sisquoc nor the upper Careaga formations will retain water in unlined ponds (PCE 1); thus, ponds require special management in the form of artificial lining with materials such as clay or butyl rubber sheeting. Pond elevations range from 500 to 1400 ft (152 to 427 m). The documented breeding localities are all stock ponds, most of which were constructed in the mid to late 1950s (Thomas Silva, Sr., pers. comm. 2001); of these, only one may have been based on a preexisting natural depression.

This unit contains the primary constituent elements essential for the conservation of the California tiger salamander. Although the occupied ponds in this unit are human made and thus require frequent maintenance, the unit is the most remote of all the units and has the fewest documented threats. Because of the steepness of the topography, conversion to farmland or high-intensity development is not feasible. However, the Service is aware of a recent proposal to develop ranchette-style houses throughout this unit within California tiger salamander dispersal distance of known ponds (Service files). The Service has not received a final proposal. The unit is unique in that it contains habitat unlike the other 5 units; it is steeper terrain and is more densely vegetated than all other units. This location contains the only known California tiger salamander breeding ponds completely surrounded by coastal sage chaparral vegetation. Few other locations in Santa Barbara County are within chaparral or mixed chaparral habitats.

The Purisima Hills Unit is also essential in that it provides a linkage between the Santa Rita Valley Unit to the southwest and the Western Los Alamos/Careaga Unit to the north. Although many of the units may be permanently separated from each other by urban development and State Highway 101, these three units still likely retain some connectivity. Several stockponds that have never been surveyed lie between the units; genetic exchange between the two critical habitat units.

The unit requires special management to address threats of habitat loss.

Unit 6: Santa Rita Valley

Modifications were made to this unit to exclude an area on the edge of the unit that does not contain the primary constituent elements. This area was included in the proposed designation as a result of a mapping error. This modification resulted in the reduction from 744 ac (301 ha) to 638 ac (258 ha).

This 638-ac (258-ha) unit constitutes the southernmost locality for California tiger salamanders in Santa Barbara County. The unit is bisected by Highway 246, a heavily traveled thoroughfare between the towns of Buellton and Lompoc. Two confirmed breeding locations (representing three ponds) lie in the Santa Rita Valley. However, one of these is a human-made pond isolated from other units and is not included within the boundaries of critical habitat. The other confirmed breeding locality consists of two hydrobasins within 50 ft (15 m) of one another and adjacent to Highway 246. Adult California tiger salamanders were often found dead on roads after rain events during the 1980s. Three ponds on a neighboring property to the east and two ponds on the south side of Highway 246 likely formed a complex with this pond in the past. However, the ponds to the east were degraded by introduced fish and vineyards, while Highway 246 forms a substantial barrier to the southern ponds. The ponds south of Highway 246 have never been surveyed for California tiger salamanders. Although one landowner reported finding a California tiger salamander in a water pump in 2000, we have been unable to obtain permission to conduct surveys to confirm or refute this record.

The known ponds are based on natural features developed on an active syncline in the Careaga Formation east of the Santa Rita-Drum Canyon divide along the north side of California Highway 246. The ponds are natural but have been excavated so that the smaller pond appears to retain water year round.

This unit contains primary constituent elements essential to the conservation of the California tiger salamander because it constitutes the only extant subpopulation remaining within the Santa Rita Valley. As stated previously, given the small number of remaining breeding locations, all six units contain primary constituent elements that are essential. In addition, due to the numbers of salamanders found dead on the roads in the 1980s, the ponds were likely productive in the past. Highway 246 constitutes the main threat to the breeding location. Furthermore, Caltrans has proposed to widen this road, which would substantially infringe on the footprint of the ponds. Even without widening, the mortality by vehicular traffic and contaminated runoff entering the pond provide substantial threats to the breeding site.

Because of the known threats due to the existence of the highway and the likelihood of section 7 consultations related to its widening it is likely that a number of special management requirements would result from consultations. The precarious position of the pond directly adjacent to a busy road may require measures to reduce the threat of contaminants entering the pond and to enhance survival of California tiger salamanders attempting to cross the road. In addition, connectivity to potential breeding locations to the south of the highway should be facilitated in some manner (PCE 3).

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7 of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify critical habitat. In response to recent court decisions invalidating our regulatory definition of adverse modification under 402.2, we are not relying on that definition in this discussion of critical habitat effects. Instead in evaluating whether destruction or adverse modification of critical habitat would occur, we rely on the statutory definition of critical habitat quoted earlier in this rule. We must analyze whether, if a proposed Federal agency action were implemented, critical habitat would remain functional to serve its intended conservation role for the species.

Section 7(a) of the Act requires Federal agencies, including the Service, to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is proposed or designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. Conference reports provide conservation recommendations to assist the agency in eliminating conflicts that may be caused by the proposed action. The

conservation recommendations in a conference report are advisory. If a species is listed or critical habitat is designated, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Through this consultation, the action agency ensures that the permitted actions do not destroy or adversely modify critical habitat.

When we issue a biological opinion concluding that a project is likely to result in the destruction or adverse modification of critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. ''Reasonable and prudent alternatives'' are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Director believes would avoid destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where critical habitat is subsequently designated and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiation of consultation or conference with us on actions for which formal consultation has been completed, if those actions may affect designated critical habitat or adversely modify or destroy proposed critical habitat.

We may issue a formal conference report if requested by a Federal agency. Formal conference reports on proposed critical habitat contain an opinion that is prepared according to 50 CFR 402.14, as if critical habitat were designated. We may adopt the formal conference report as the biological opinion when the critical habitat is designated, if no substantial new information or changes in the action alter the content of the opinion (see 50 CFR 402.10(d)).

Activities on Federal lands that may affect this species or its critical habitat will require section 7 consultation. Activities on private or State lands requiring a permit from a Federal agency, such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act, a section 10(a)(1)(B) permit from the Service, or some other Federal action, including funding (*e.g.*, Federal Highway Administration or Federal Emergency Management Agency funding), will also continue to be subject to the section 7 consultation process. Federal actions not affecting listed species or critical habitat and actions on non-Federal and private lands that are not federally funded, authorized, or permitted do not require section 7 consultation.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe in any proposed or final regulation that designates critical habitat those activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation. Activities that may destroy or adversely modify critical habitat include those that would impair the functionality of the primary constituent elements within a critical habitat unit to serve their intended conservation role for the species. We note that such activities may also jeopardize the continued existence of the species.

To properly portray the effects of critical habitat designation, we must first compare the section 7 requirements for actions that may affect critical habitat with the requirements for actions that may affect a listed species. Section 7 prohibits actions funded, authorized, or carried out by Federal agencies from jeopardizing the continued existence of a listed species or destroying or adversely modifying the listed species' critical habitat.

Federal agencies already consult with us on activities in areas currently occupied by the species to ensure that their actions do not jeopardize the continued existence of the species. Actions that may affect critical habitat include, but are not limited to:

(1) Actions that would affect waters of the United States by the Army Corps under section 404 of the Clean Water Act. Such activities could include, but are not limited to, erosion control activities and flood control activities. These activities could eliminate or reduce the habitat necessary for the reproduction or growth of California tiger salamanders.

(2) Actions that would affect the regulation of water flows by any Federal agency. Such activities could include, but are not limited to, damming, diversion, and channelization. These activities could eliminate or reduce the habitat necessary for the reproduction or growth of California tiger salamanders.

(3) Actions that would involve regulations funded or permitted by the Federal Highway Administration. (We note that the Federal Highway Administration does not fund the routine operations and maintenance of the State highway system.) Such activities could include, but are not limited to, new road construction and right-of-way designation. These activities could eliminate or reduce the upland habitat and/or dispersal habitat necessary for sheltering and foraging of California tiger salamanders, and necessary for connectivity between aquatic breeding habitats.

(4) Actions that would involve voluntary conservation measures by private landowners funded by the Natural Resources Conservation Service. Such activities could include, but are not limited to, stockpond maintenance and erosion control practices. These activities could eliminate or reduce upland and/or aquatic habitat for the California tiger salamander.

(5) Actions that would involve regulation of airport improvement activities by the Federal Aviation Administration. Such activities could include, but are not limited to, the creation or expansion of airport facilities. These activities could eliminate or reduce upland and/or aquatic habitat for the California tiger salamander.

(6) Actions that would involve licensing of construction of communication sites by the Federal Communications Commission. Such activities could include, but are not limited to, the installation of new radio equipment and facilities. These activities could eliminate or reduce the habitat necessary for the reproduction, sheltering, foraging, or growth of California tiger salamanders.

(7) Actions that would involve funding of activities by the U.S. Environmental Protection Agency, Department of Energy, Federal Emergency Management Agency, Federal Highway Administration, or any other Federal agency. Such activities could include, but are not limited to, activities associated with the cleaning up of Superfund sites, erosion control activities, and flood control activities. These activities could eliminate or reduce upland and/or aquatic habitat for the California tiger salamander.

The six critical habitat units are occupied by the species based on

observations made within the last four years. Additionally, all habitats within this designation are likely to be used by the California tiger salamander, whether for foraging, breeding, growth of larvae and juveniles, dispersal, migration, genetic exchange, or sheltering. Thus, all critical habitat units are occupied by the species. Federal agencies already consult with us on activities in areas currently occupied by the species or if the species may be affected by the action, to ensure that their actions do not jeopardize the continued existence of the species.

Exclusions Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that critical habitat shall be designated, and revised, on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. An area may be excluded from critical habitat if it is determined that the benefits of exclusion outweigh the benefits of specifying a particular area as critical habitat, unless the failure to designate such area as critical habitat will result in the extinction of the species.

In our critical habitat designations, we use both the provisions outlined in sections 3(5)(A) and 4(b)(2) of the Act to evaluate those specific areas that we are considering proposing designating as critical habitat as well as for those areas that are formally proposed for designation as critical habitat. Lands we have found do not meet the definition of critical habitat under section 3(5)(A) or have excluded pursuant to section 4(b)(2) include those covered by the following types of plans if they provide assurances that the conservation measures they outline will be implemented and effective: (1) Legally operative HCPs that cover the species, (2) draft HCPs that cover the species and have undergone public review and comment (*i.e.*, pending HCPs), (3) Tribal conservation plans that cover the species, (4) State conservation plans that cover the species, and (5) National Wildlife Refuge System Comprehensive Conservation Plans.

Conservation Strategies

We are excluding three properties from this final critical habitat designation that have conservation strategies in place for the California tiger salamander because we believe that they are appropriate for exclusion pursuant to the ''other relevant factor'' provisions of section 4(b)(2).

One landowner, Mr. Scheller, in Unit 5 (Purisima Hills), has developed a conservation strategy for his property which supports the large natural vernal lake referred to as Laguna Seca (LOAL–11 on the Santa Barbara County California Tiger Salamander Habitat Map, August 2001), its essential associated watershed, and other bodies of water that could potentially be used for breeding by the California tiger salamander. Although Laguna Seca did not contain California tiger salamanders during surveys conducted in 2002, it was likely the natural source of California tiger salamanders for the human-made ponds in the Purisima Hills to the south and southwest of the pond. Largemouth bass (*Micropterus salmoides*) and mosquitofish were recorded during surveys in 2002 (Paul Collins, Santa Barbara Museum of Natural History, pers. comm. 2002). The introduced fish likely preclude successful breeding, although adult California tiger salamanders are likely present in the adjacent uplands, given the successful breeding occurring in the other known ponds in the vicinity. Special management is needed to remove introduced fish from Laguna Seca. In the conservation strategy developed with Mr. Scheller, the landowner proposes special management considerations and protections for the California tiger salamander habitat on his property.

The goals of the above conservation strategy for the Scheller property include:

(1) Manage livestock grazing activities and maintenance of water sources in a way that is compatible with California tiger salamander in Santa Barbara County;

(2) Manage to limit sediment input into the known and potential breeding ponds;

(3) Limited or restricted use of chemicals within the watershed and/or within 2,200 ft (671 m) of the known and potential breeding ponds;

(4) Use other methods compatible with the California tiger salamander to control the amount of vegetation around the known and potential breeding ponds if livestock are not available; and

(5) Avoid introducing non-native predators into the known and potential breeding ponds.

Kendall-Jackson Wine Estates, Ltd. (Kendall-Jackson) leases certain property in Unit 3 (Western Los Alamos/Careaga) and Unit 4 (Eastern Los Alamos). The property in Unit 3 (hereinafter, the Sainz property) is owned by the Darwin E. Sainz 1990 Trust, Darwin E. Sainz and Jeanette T. Sainz, trustees (hereinafter, the Sainz Family). The property in Unit 4 (hereinafter the Los Robles property) is owned by Jackson Family Investments II, LLC, an affiliate of Kendall-Jackson. Kendall-Jackson, in conjunction with each of these property owners, has developed a conservation plan for these properties. The Sainz property includes three known California tiger salamander breeding ponds (SISQ–1, SISQ–2, and SISQ–4, as referenced on the Santa Barbara County California Tiger Salamander Habitat Map, August 2001) and their essential associated watersheds. This area, located in the southeastern half of the Western Los Alamos/Careaga subpopulation, was proposed for conversion to vineyards prior to the listing of the salamander. Since listing, the lessee and the landowner have supported California tiger salamander conservation and have been working towards developing a vineyard proposal that would conserve California tiger salamanders breeding in the known ponds. We have worked with the landowner in this area on an erosion control project within the associated watershed of SISQ–1. In the conservation strategy for this property, special management considerations and protections are proposed for the California tiger salamander habitat.

The Los Robles property in Unit 4 (Eastern Los Alamos) contains all four known California tiger salamander ponds in this subpopulation (LOAL–18, LOAL–19, ZACA–3, and ZACA–5, as referenced on the Santa Barbara County California Tiger Salamander Habitat Map, August 2001). Two of the ponds (LOAL–18 and LOAL–19) are natural structural basin ponds found in depressions. The other two ponds (ZACR–3 and ZACR–5) are bermed agricultural impoundments located in an unnamed, intermittent drainage located 1.0 to 1.5 miles southeast of the two natural ponds. In the conservation strategy for this property, Kendall-Jackson and its affiliate, the property owner, have agreed to special management considerations and protections for the California tiger salamander habitat. The Service and Kendall-Jackson are in the process of discussing further conservation opportunities for this property in connection with a development project recently proposed by Kendall-Jackson.

The goals of the above conservation strategies for the Sainz property and the Los Robles property include:

(1) Elimination of sediment input into the known and potential breeding ponds;

(2) Limited or restricted use of chemicals within the watershed and/or

within 2,200 ft (671 m) of the known and potential breeding ponds;

(3) Use other methods compatible with the California tiger salamander to control the amount of vegetation around the known and potential breeding ponds if livestock are not available;

(4) Enhancement of existing aquatic habitat and, in the case of the Los Robles property, creation of new aquatic habitat; and

(5) Avoiding the introduction of non-native predators into the known and potential breeding ponds.

(1) Benefits of Inclusion

Designation of critical habitat provides important information on those habitats and their primary constituent elements that are essential to the conservation of the species. This information is particularly important to any Federal agency, State, county, local jurisdiction, conservation organization, or private landowner that may be evaluating adverse actions or implementing conservation measures that involve those habitats. The benefit of a critical habitat designation would ensure that any actions authorized, funded, or carried out by a Federal agency would not likely destroy or adversely modify any critical habitat. All habitats within this designation are occupied. In the absence of critical habitat, any section 7 consultation for potential adverse effects to the species would not ensure adverse modification of critical habitat is avoided; however, the consultation would ensure the proposed action would not jeopardize the continued existence of the species in the wild.

Where conservation strategies are in place, our experience indicates that this benefit is small or non-existent. Currently approved conservation strategies are already designed to ensure the long-term survival of covered species within the plan area. Where we have an approved conservation strategy, lands that we ordinarily would define as critical habitat for covered species will normally be protected by the terms of the conservation strategy. These conservation strategies include management measures designed to protect, restore, and enhance the land's value as habitat for covered species. We have determined that the benefits of designating critical habitat on the three properties covered by the described conservation strategies are small.

(2) Benefits of Exclusion

Approximately 80 percent of imperiled species in the United States occur partly or solely on private lands where the Service has little management authority (Wilcove *et al.* 1996). Proactive voluntary conservation efforts are necessary to prevent the extinction and promote the recovery of the California tiger salamander on private lands in northern Santa Barbara County.

The Service believes that the California tiger salamander populations within the properties with conservation strategies will benefit substantially from landowner voluntary management actions due to a reduction in competition with non-native predators, a reduction in risk of chemically-altered aquatic habitats, a reduction in risk of loss of aquatic and upland habitat, and the enhancement and creation of aquatic habitat. The conservation benefits of critical habitat are primarily regulatory or prohibitive in nature. Where consistent with the discretion provided by the Act, the Service believes it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove *et al.* 1998). Thus, we believe it is essential for the recovery of the California tiger salamander in Santa Barbara County to build on continued conservation activities such as these with a proven partner, and to provide positive incentives for other private landowners in Santa Barbara County who might be considering implementing voluntary conservation activities but have concerns about incurring incidental regulatory or economic impacts.

In addition, recovery actions involving the enhancement and creation of aquatic habitat on private lands requires the voluntary cooperation of the landowner (Bean 2002; James 2002; Knight 1999; Main *et al.* 1999; Norton 2000; Shogren *et al.* 1999; Wilcove *et al.* 1998). Therefore, ''a successful recovery program is highly dependent on developing working partnerships with a wide variety of entities, and the voluntary cooperation of thousands of non-Federal landowners and others is essential to accomplishing recovery for listed species'' (Crouse *et al.* 2002). The land within this designation that is suitable for conservation of threatened and endangered species is mostly owned by private landowners; therefore, successful recovery of the California tiger salamander in northern Santa Barbara County is especially dependent upon working partnerships and the voluntary cooperation of non-Federal landowners.

(3) The Benefits of Exclusion Outweigh the Benefits of Inclusion

Based on the above considerations, and consistent with the direction provided in section 4(b)(2) of the Act and the recent Federal District Court decision concerning critical habitat (*Center for Biological Diversity* v. *Norton*, Civ. No. 01–409 TUC DCB D. Ariz. Jan. 13, 2003), we have determined that the benefits of excluding the Scheller property in Unit 2, the Sainz property in Unit 3, and the Los Robles property in Unit 4 as critical habitat outweigh the benefits of including them as critical habitat for the California tiger salamander in Santa Barbara County.

This conclusion is based on the following factors:

1. The Scheller, Sainz, and Los Robles properties are currently being managed on a voluntary basis in cooperation with the Service, State, and other private organizations to achieve important conservation goals.

2. Simple regulation of ''harmful activities'' is not sufficient to conserve these species. Landowner cooperation and support are required to prevent the extinction and promote the recovery of all of the listed species in northern Santa Barbara County due to the need to implement proactive conservation actions such as predator management, weed control, and aquatic habitat enhancement and creation. Exclusion of these properties from this critical habitat designation will help the Service maintain and improve this partnership by formally recognizing the positive contributions of Mr. Scheller, the Sainz Family and Kendall-Jackson and its affiliate to the recovery of the California tiger salamander in Santa Barbara County, and by streamlining or reducing unnecessary regulatory oversight.

3. Given the current conservation strategies created and implemented by Mr. Scheller, the Sainz Family and Kendall-Jackson, the Service believes the additional regulatory and educational benefits of including these lands as critical habitat are relatively small. The designation of critical habitat can serve to educate the general public as well as conservation organizations regarding the potential conservation value of an area, but this goal is already being accomplished through the identification of this area in the management plans described above. Likewise, there will be little additional Federal regulatory benefit to the species because all units are already occupied by the California tiger salamander and a section 7 nexus already exists. The Service is unable to identify any other

potential benefits associated with critical habitat for these properties.

4. Excluding these privately-owned lands with conservation strategies from critical habitat may, by way of example, provide positive social, legal, and economic incentives to other non-Federal landowners in northern Santa Barbara County who own lands that could contribute to listed species recovery if voluntary conservation measures on these lands are implemented (Norton 2000; Main *et al.* 1999; Shogren *et al.* 1999; Wilcove and Chen 1998).

In conclusion, we find that the exclusion of critical habitat on Mr. Scheller's property, the Sainz property, and the Los Robles property would most likely have a net positive conservation effect on the recovery and conservation of the California tiger salamander in Santa Barbara County when compared to the positive conservation effects of a critical habitat designation. As described above, the overall benefits to these species of a critical habitat designation for these properties are relatively small. In contrast, we believe that this exclusion will enhance our existing partnership with these landowners, and it will set a positive example and provide positive incentives to other non-Federal landowners who may be considering implementing voluntary conservation activities on their lands. We conclude there is a higher likelihood of beneficial conservation activities occurring in these and other areas of northern Santa Barbara County without designated critical habitat than there would be with designated critical habitat on these properties.

(4) Exclusion of This Unit Will Not Cause Extinction of the Species

In considering whether or not exclusion of these properties might result in the extinction of this species, the Service considered the impacts to the California tiger salamander. For the California tiger salamander populations located within the Western Los Alamos Unit, East Los Alamos Unit, and Purisima Hills Unit, it is the Service's conclusion that the conservation strategies agreed to by the landowners and, where applicable, lessees will provide as much or more net conservation benefits as would be provided if these preserves were designated as critical habitat. These conservation strategies, which are described above, will provide tangible proactive conservation benefits that will reduce the likelihood of extinction for the California tiger salamander in Santa Barbara County and increase its likelihood of recovery. Extinction for this species as a consequence of this exclusion is unlikely because there are no known threats on these properties due to any current or reasonably anticipated Federal actions that might be regulated under section 7 of the Act. Further, these areas are already occupied and thereby benefit from the section 7 protections of the Act, should such an unlikely Federal threat actually materialize. The exclusion of these preserves will not increase the risk of extinction to this species, and it may increase the likelihood this species will recover by encouraging other landowners to implement voluntary conservation activities as Mr. Scheller, the Sainz Family, and Kendall-Jackson and its affiliate have done. In sum, the above analysis concludes that an exclusion of these properties from final critical habitat for the California tiger salamander in northern Santa Barbara County will have a net beneficial impact with little risk of negative impacts. Therefore, the exclusion of these lands will not cause extinction and should in fact improve the chances of recovery for California tiger salamander.

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial information available and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as part of critical habitat. We cannot exclude such areas from critical habitat if such exclusion would result in the extinction of the species.

Following the publication of the proposed critical habitat designation, we conducted an economic analysis to estimate the potential economic effect of the designation. The draft analysis was made available for public review on October 7, 2004. We accepted comments on the draft analysis until November 8, 2004.

Our proposed critical habitat rule pertained to the Santa Barbara County population of California tiger salamander. Therefore, our economic analysis evaluated the potential future effects associated with the listing of this species as endangered under the Act, as well as any potential effect of the critical habitat designation above and beyond those regulatory and economic impacts associated with listing.

We received 18 comments on the draft economic analysis of the proposed designation. Following the close of the comment period, we considered comments, prepared responses to comments, and prepared a summary of revisions to economic issues based on final critical habitat designation. See *Responses to Comments* section above.

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this document is a significant rule in that it may raise novel legal and policy issues, but it is not anticipated to have an annual effect on the economy of $100 million or more or affect the economy in a material way. Due to the tight timeline for publication in the **Federal Register**, the Office of Management and Budget (OMB) has not formally reviewed this rule. We prepared a draft economic analysis of this proposed action to determine the economic consequences of designating the specific area as critical habitat. The draft economic analysis was made available for public comment, and we considered those comments during the preparation of this rule. The economic analysis indicates that this rule will not have an annual economic effect of $100 million or more. The economic employs a lower and upper scenario approach to the economic costs associated with each unit. The lower scenario is based on the development of all land that is currently zoned for residential, commercial, or industrial development by 2030. The upper scenario, which applies to only units 1, 2, and 4, is based on the possibility that, in addition to the land already zoned for development (lower scenario), large amounts of additional agricultural lands within these units will also be developed. Based on the more certain lower scenario, the annualized economic effects of this designation are estimated to be $8,962,250; the estimate for the upper scenario is $35,369,906. We have excluded 2,740 ac (1,109 ha) of privately owned lands analyzed in the draft economic analysis based on non-economic considerations so the direct economic impacts of the final designation is likely to be lower than this estimate. This is based on 26-year estimates.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare

and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the Regulatory Flexibility Act (RFA) to require Federal agencies to provide a statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Regulatory Enforcement Fairness Act amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that the rule will not have a significant economic effect on a substantial number of small entities. The Small Business Regulatory Enforcement Fairness Act also amended the Regulatory Flexibility Act to require a certification statement. We are hereby certifying that this rule will not have a significant effect on a substantial number of small entities.

The Small Business Regulatory Enforcement Fairness Act does not explicitly define either ''substantial number'' or ''significant economic impact.'' Consequently, to assess whether a ''substantial number'' of small entities is affected by this designation, this analysis considers the relative number of small entities likely to sustain impacts in the area. Similarly, this analysis considers the relative cost of compliance on the revenues/profit margins of small entities in determining whether or not entities incur a ''significant economic impact.'' Only small entities that are expected to be directly affected by the designation are considered in this portion of the analysis. This approach is consistent with several judicial opinions related to the scope of the Regulatory Flexibility Act (*Mid-Tex Electric Co-Op, Inc.* v. *FERC* and *American Trucking Associations, Inc.* v. *EPA*).

According to the Small Business Administration, small entities include small organizations, such as independent nonprofit organizations, and small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents, as well as small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we consider the types of activities that might trigger regulatory impacts under this rule as well as the types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

To determine if the rule would affect a substantial number of small entities, we consider the number of small entities affected within particular types of economic activities (*e.g.*, housing development, grazing, oil and gas production, timber harvesting, etc.). In estimating the numbers of small entities potentially affected, we also consider whether their activities have any Federal involvement; some kinds of activities are unlikely to have any Federal involvement and so will not be affected by critical habitat designation.

Designation of critical habitat only affects activities carried out, authorized, or funded by Federal agencies; non-Federal activities are not affected by the designation. In areas where the species are present, Federal agencies are already required to consult with us under section 7 of the Act on activities that they carry out, authorize, or fund that may affect the Santa Barbara population of the California tiger salamander. When these critical habitat designations are finalized, Federal agencies must also consult with us if their activities may affect designated critical habitat. However, in areas where the species are present, we do not believe this will result in appreciable additional regulatory burdens on Federal agencies or their applicants because consultation would already be required because of the presence of the listed species.

Based on the economic analysis, the land development industry and the viticulture industry may contain small entities potentially affected by California tiger salamander conservation activities. We address the potential impacts to small businesses in each of these industries below.

Land Development Small Business Impacts

The SBA's size standards for private sector firms are based on the North American Industry Classification System (NAICS). The economic analysis identified NAICS Code number 237210 as most appropriate for analysis of land development impacts. According to the SBA size criterion, firms in this industry must have less than $6 million per year in gross revenues to be considered a small business. Although, under the RFA, individual landowners are not considered businesses, the economic analysis assumes that all landowners affected by California tiger salamander conservation in Santa Barbara County are businesses, which is likely to overstate the actual impacts to small land development firms. Based on this assumption, 97 percent of the land development firms in Santa Barbara County are small businesses. However, the share of total sales in the land development industry attributable to small businesses is approximately 54 percent. Thus, although the small businesses constitute a relatively large share of the total businesses, their share of total sales is significantly lower. For the land development industry, the total small business impact of California tiger salamander conservation is estimated to be about $4.5 million for the lower scenario in Santa Barbara County. The number of small land developers affected by California tiger salamander conservation annually is 3 percent of the total for the county for the lower scenario. If the upper scenario were to occur, the impacts to small land development firms would be considerably higher.

Viticulture Small Business Impacts

According to the SBA size criterion, firms in the viticulture industry are considered small when fewer than 500 individuals are employed by the firm. Based on this size classification, all of the viticulture firms in Santa Barbara County are small businesses. For the viticulture industry, the total small business impact of California tiger salamander conservation is estimated to be about $467,000 in Santa Barbara County. The number of small viticulture firms affected by salamander conservation annually is about 1 percent of the typical annual sales for a small business in this industry.

In summary, we have considered whether this rule would result in a significant economic effect on a substantial number of small entities. We have concluded that this final designation of critical habitat for the California tiger salamander would not affect a substantial number of small entities. Therefore, we are certifying that the designation of critical habitat for the salamander will not have a significant economic impact on a substantial number of small entities, and a final

regulatory flexibility analysis is not required.

Executive Order 13211

On May 18, 2001, the President issued Executive Order 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This final rule to designate critical habitat for the California tiger salamander is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501), the Service makes the following findings:

(a) This rule does not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, tribal governments, or the private sector and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; AFDC work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply; nor would critical habitat shift the costs of the large entitlement programs listed above on to State governments.

(b) Due to current public knowledge of the species' protection, and the prohibition against take of the species both within and outside of the designated areas, we do not anticipate that this rule will significantly or uniquely affect small governments. As such, a Small Government Agency Plan is not required.

Takings

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of designating critical habitat for the Santa Barbara population of the California tiger salamander in a takings implication assessment, which indicates that this rule would not pose significant takings implications. The takings implications assessment concludes that this final designation of critical habitat for the salamander does not pose significant takings implications.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with the Department of the Interior policies, we requested information from, and coordinated development of, this critical habitat designation with appropriate State resource agencies in California. The designation of critical habitat in areas currently occupied by the Santa Barbara County population of California tiger salamander imposes no additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to the States and local resource agencies in that the areas essential to the conservation of the species are more clearly defined, and the primary constituent elements of the habitat necessary to the survival of the species are specifically identified. While making this definition and identification does not alter where and what federally sponsored activities may occur, it may assist local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with Executive Order 12988, the Department of the Interior's Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Endangered Species Act. This rule uses standard property descriptions and identifies the primary constituent elements within the designated areas to assist the public in understanding the habitat needs of the Santa Barbara County population of California tiger salamander.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain new or revised information collection for which OMB approval is required under the Paperwork Reduction Act. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

It is our position that, outside the Tenth Circuit, we do not need to prepare environmental analyses as defined by the NEPA in connection with designating critical habitat under the Endangered Species Act of 1973, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County* v.

Babbitt, 48 F.3d 1495 (9th Cir. Ore. 1995), cert. denied 116 S. Ct. 698 (1996).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we have coordinated with federally recognized Tribes on a Government-to-Government basis. We have determined that there are no tribal lands essential for the conservation of the Santa Barbara County population of California tiger salamander. Therefore, we have not designated any critical habitat for the Santa Barbara County population of California tiger salamander on Tribal lands.

References Cited

A complete list of all references cited in this rulemaking is available upon request from the Field Supervisor, Ventura Fish and Wildlife Office (*see* **ADDRESSES** section).

Author(s)

The primary author of this package is the U.S. Fish and Wildlife Service.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

■ For the reasons outlined in the preamble, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. In § 17.11(h), revise the entry for ''Salamander, California tiger'' under ''AMPHIBIANS'' to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
AMPHIBIANS							
*	*	*	*	*	*		*
Salamander, California tiger, Santa Barbara County Population.	*Ambystoma californiense*.	U.S.A. (CA)	U.S.A. (CA—California).	T	667E, 702, 744	17.95(d)	17.43(c)
*	*	*	*	*	*		*

* * * * *

■ 3. Amend § 17.95(d) by adding critical habitat for the California tiger salamander (*Ambystoma californiense*) under ''AMPHIBIANS'' in the same alphabetical order as the species occurs in § 17.11(h) to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(d) Amphibians.

* * * * *

California tiger salamander (*Ambystoma californiense*) in Santa Barbara County

(1) Critical habitat units are depicted for Santa Barbara County, California, on the maps below.

(2) The primary constituent elements (PCEs) of critical habitat for the California tiger salamander in Santa Barbara County are the habitat components that provide:

(i) Standing bodies of fresh water, including natural and man-made (*e.g.*, stock) ponds, vernal pools, and dune ponds, and other ephemeral or permanent water bodies that typically become inundated during winter rains and hold water for a sufficient length of time (*i.e.*, 12 weeks) necessary for the species to complete the aquatic portion of its life cycle (PCE 1).

(ii) Barrier-free uplands adjacent to breeding ponds that contain small mammal burrows, including but not limited to burrows created by the California ground squirrel (*Spermophilus beecheyi*) and Botta's pocket gopher (*Thommomys bottae*). Small mammals are essential in creating the underground habitat that adult California tiger salamanders depend upon for food, shelter, and protection from the elements and predation (PCE 2).

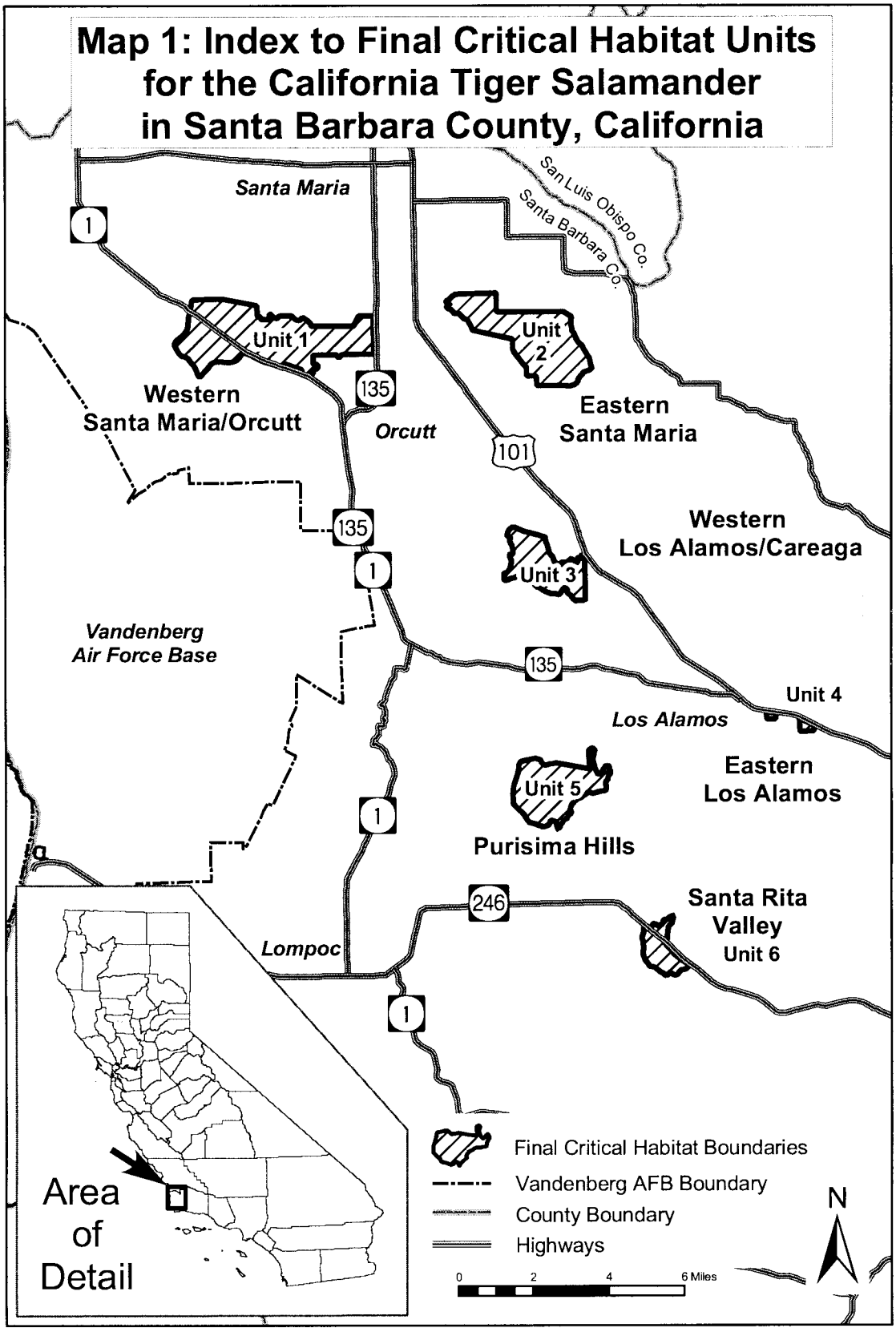
(iii) Upland areas between breeding locations (PCE 1) and areas with small mammal burrows (PCE 2) that allow for dispersal among such sites (PCE 3).

(3) Critical habitat does not include existing features and structures, such as buildings, aqueducts, airports, roads and their rights of way, and other developed areas not containing one or more of the primary constituent elements.

(4) Final critical habitat units are described below. Coordinate in UTM Zone 10 with units in meters using North American Datum of 1927 (NAD27).

(5) **Note:** Map 1 (Index map) follows:

BILLING CODE 4310–55–P

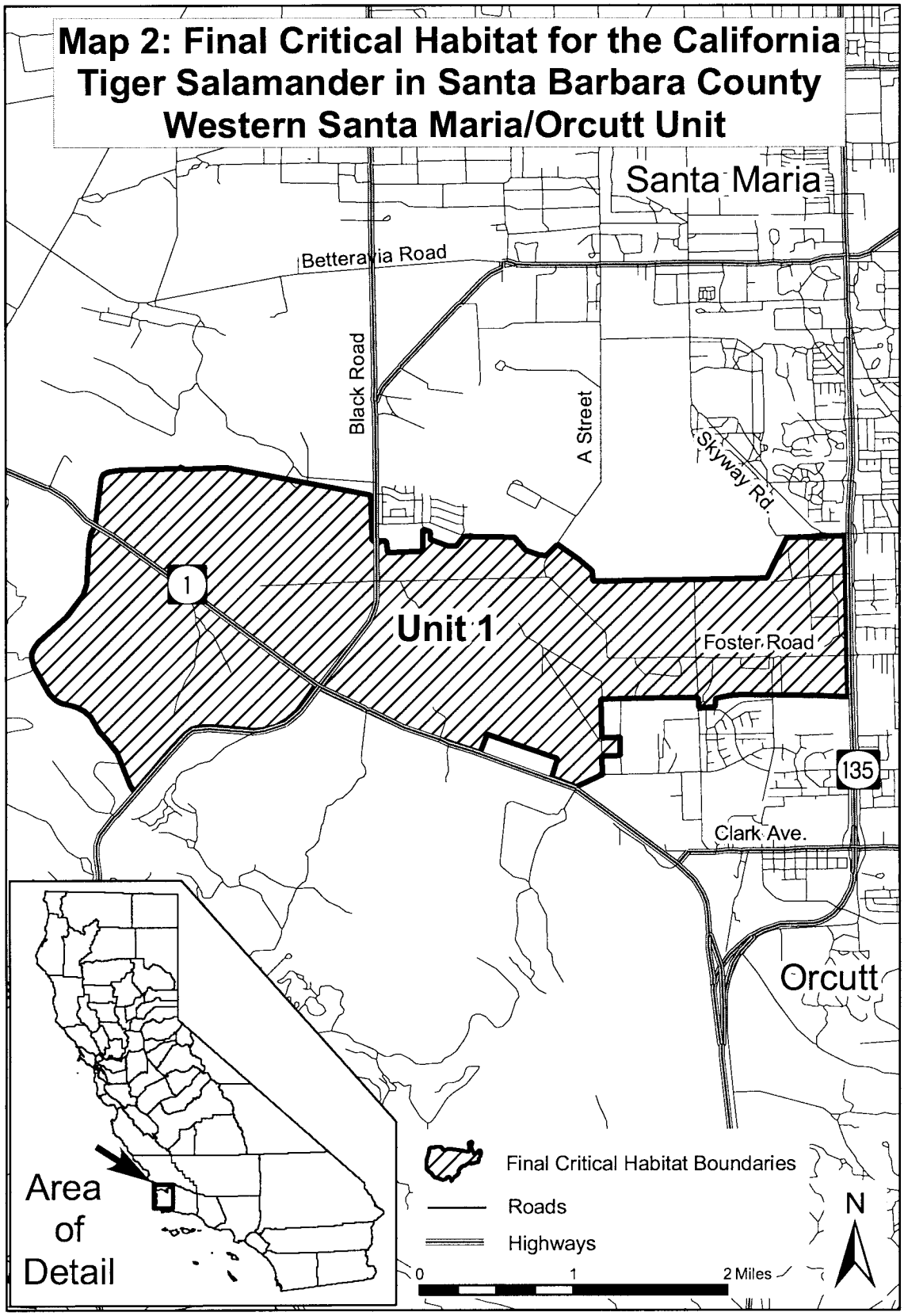


(6) Unit 1: Western Santa Maria/Orcutt Unit, Santa Barbara County, California.

(i) From USGS 1:24, 000 scale quadrangle maps Guadalupe, Santa Maria, Orcutt and Casmalia. Lands bounded by UTM Zone 10, NAD 1927 coordinates (E, N): 727389, 3864869; 727442, 3864843; 727875, 3864859;

729380, 3864569; 729392, 3864085; 729538, 3864085; 729549, 3863963; 729918, 3863978; 729917, 3864206; 729992, 3864189; 729994, 3864102; 730189, 3864034; 730274, 3864033; 730349, 3864133; 730426, 3864139; 730428, 3864131; 730875, 3864121; 730995, 3863984; 731124, 3863944; 731211, 3863935; 731326, 3864047; 731326, 3864050; 731327, 3864050; 731552, 3863889; 731688, 3863776; 731694, 3863667; 732718, 3863684; 733501, 3863695; 733710, 3864115; 734321, 3864137; 734356, 3862460; 734012, 3862472; 733226, 3862481; 733120, 3862472; 732971, 3862446; 732961, 3862352; 732793, 3862347; 732789, 3862453; 732392, 3862448; 731780, 3862433; 731777, 3862409; 731782, 3862099; 731782, 3862030; 731972, 3862034; 731974, 3861846; 731788, 3861839; 731793, 3861647; 731514, 3861520; 731262, 3861619; 731322, 3861818; 730590, 3862072; 730517, 3861874; 730107, 3862013; 729738, 3862138; 729602, 3862197; 729340, 3862322; 729093, 3862435; 728920, 3862517; 728803, 3862577; 728697, 3862427; 728611, 3862313; 728499, 3862215; 728390, 3862156; 728264, 3862119; 728151, 3862116; 728010, 3862126; 727823, 3862142; 727665, 3862155; 727578, 3862147; 727520, 3862128; 727450, 3862077; 727373, 3861996; 727263, 3861874; 726913, 3861473; 726869, 3861542; 726733, 3861881; 726625, 3862026; 726543, 3862111; 726454, 3862257; 726385, 3862323; 726312, 3862358; 726267, 3862377; 726195, 3862392; 726144, 3862402; 726090, 3862433; 726030, 3862494; 725866, 3862781; 725844, 3862860; 725847, 3862927; 725875, 3862987; 725916, 3863037; 726214, 3863309; 726378, 3863531; 726419, 3863641; 726444, 3864049; 726467, 3864173; 726511, 3864261; 726568, 3864745; 726596, 3864786; 726638, 3864810; 726727, 3864827; 726866, 3864836; 727389, 3864850; returning to coordinates 727389, 3864869.

(ii) **Note:** Unit 1 (Map 2) follows:

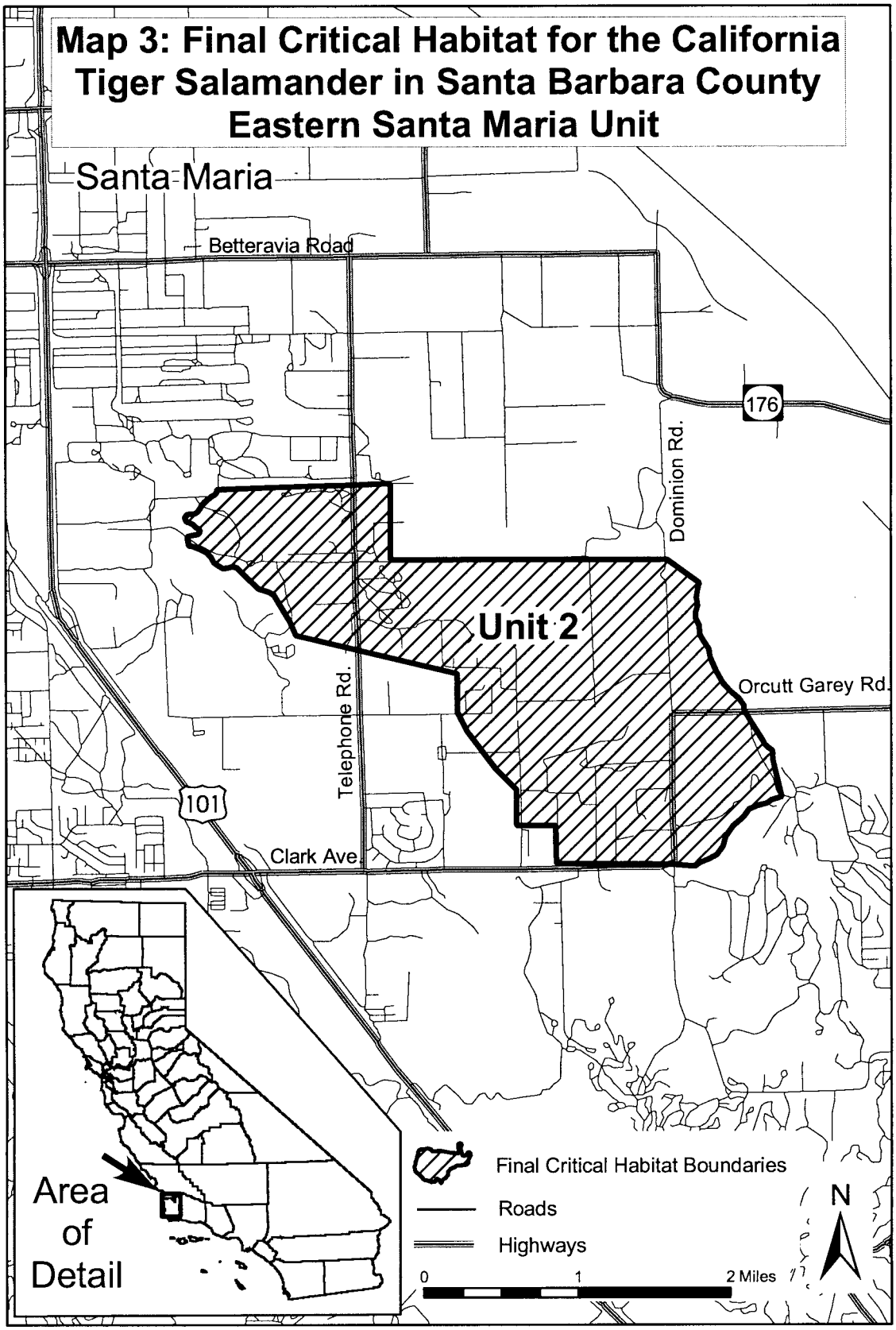


(7) Unit 2: Eastern Santa Maria Unit, Santa Barbara County, California.

(i) From USGS 1:24,000 scale quadrangle maps Guadalupe, Santa Maria, Twitchell Dam, Orcutt and Sisquoc. Lands bounded by UTM Zone

10, NAD 1927 coordinates (E, N): 737445, 3864756; 737472, 3864777; 737515, 3864783; 737548, 3864786; 737572, 3864801; 737600, 3864838; 737615, 3864865; 737648, 3864905; 737679, 3864932; 737706, 3864950; 737727, 3864968; 737755, 3864987; 737776, 3865011; 737779, 3865041; 738854, 3865078; 738849, 3865074; 739192, 3865081; 739600, 3865100; 739600, 3864300; 742500, 3864300; 742836, 3864048; 742825, 3863984; 742805, 3863899; 742825, 3863808; 742798, 3863736; 742798, 3863677; 742838, 3863599; 742851, 3863501; 742890, 3863429; 742942, 3863357; 742955, 3863266; 743020, 3863122; 743086, 3863004; 743164, 3862913; 743256, 3862841; 743308, 3862763; 743308, 3862717; 743399, 3862573; 743497, 3862417; 743536, 3862345; 743608, 3862286; 743608, 3862201; 743703, 3861803; 743680, 3861801; 743607, 3861773; 743552, 3861732; 743460, 3861709; 743363, 3861672; 743299, 3861589; 743194, 3861498; 743115, 3861392; 743083, 3861277; 743028, 3861194; 742955, 3861153; 742844, 3861112; 742794, 3861075; 742546, 3861098; 741338, 3861104; 741329, 3861505; 740918, 3861507; 740918, 3861880; 740700, 3862100; 740400, 3862500; 740300, 3862700; 740300, 3863100; 738600, 3863500; 738531, 3863657; 738371, 3863925; 738322, 3863957; 738273, 3863974; 738219, 3863986; 738136, 3864066; 738036, 3864163; 737987, 3864215; 737938, 3864226; 737890, 3864212; 737838, 3864206; 737795, 3864232; 737749, 3864266; 737718, 3864321; 737672, 3864378; 737595, 3864409; 737512, 3864441; 737493, 3864445; 737485, 3864446; 737478, 3864479; 737466, 3864522; 737472, 3864543; 737500, 3864555; 737536, 3864561; 737576, 3864571; 737600, 3864589; 737594, 3864625; 737563, 3864640; 737530, 3864668; 737487, 3864689; 737460, 3864701; 737448, 3864728; returning to coordinates 737445, 3864756

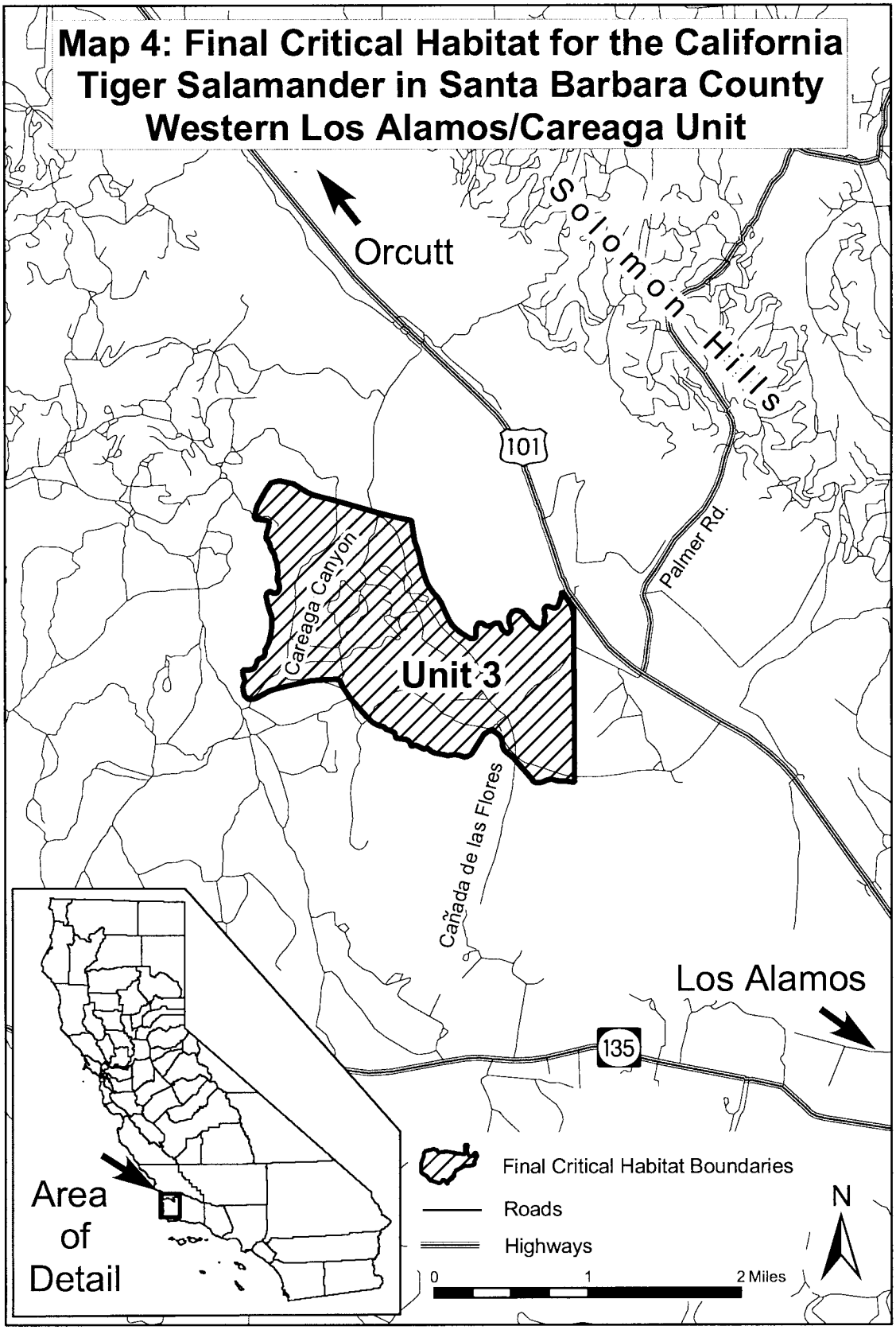
(i) **Note:** Unit 2 (Map 3) follows:


Map 3: Final Critical Habitat for the California Tiger Salamander in Santa Barbara County Eastern Santa Maria Unit
Santa Maria
Betteravia Road
176
Dominion Rd.
Unit 2
Orcutt Garey Rd.
Telephone Rd.
101
Clark Ave.
Area of Detail
Final Critical Habitat Boundaries
Roads
Highways
0
1
2 Miles
N

(8) Unit 3: Western Los Alamos/ Careaga Unit, Santa Barbara County, California.

(i) From USGS 1:24,000 scale quadrangle maps Orcutt and Sisquoc. Lands bounded by UTM Zone 10, NAD 1927 coordinates (E, N): 739930, 3852832; 739932, 3852861; 739942, 3852885; 739950, 3852898; 739953, 3852908; 739948, 3852930; 739938, 3852953; 739930, 3852980; 739930, 3853010; 739934, 3853028; 739949, 3853035; 740004, 3853033; 740031, 3853036; 740050, 3853048; 740057, 3853058; 740069, 3853085; 740079, 3853108; 740089, 3853128; 740102, 3853145; 740129, 3853157; 740152, 3853178; 740159, 3853196; 740161, 3853220; 740164, 3853243; 740194, 3853293; 740204, 3853313; 740211, 3853337; 740215, 3853373; 740224, 3853418; 740236, 3853465; 740233, 3853508; 740236, 3853551; 740232, 3853598; 740212, 3853658; 740197, 3853710; 740189, 3853748; 740175, 3853778; 740179, 3853818; 740189, 3853838; 740207, 3853850; 740227, 3853847; 740249, 3853838; 740273, 3853833; 740288, 3853838; 740309, 3853865; 740314, 3853898; 740309, 3853934; 740295, 3853970; 740295, 3854004; 740301, 3854056; 740297, 3854108; 740284, 3854159; 740273, 3854198; 740261, 3854241; 740233, 3854288; 740219, 3854318; 740219, 3854348; 740201, 3854378; 740179, 3854408; 740175, 3854438; 740185, 3854482; 740205, 3854528; 740210, 3854580; 740189, 3854598; 740138, 3854609; 740067, 3854618; 740058, 3854630; 740057, 3854650; 740068, 3854705; 740086, 3854764; 740122, 3854832; 740145, 3854873; 740171, 3854916; 740200, 3854958; 740227, 3854990; 740246, 3855003; 740268, 3855011; 740299, 3855016; 740327, 3855016; 740394, 3855002; 740463, 3854982; 740529, 3854949; 740587, 3854907; 740667, 3854871; 740749, 3854847; 740853, 3854820; 741014, 3854780; 741358, 3854674; 741546, 3854627; 741695, 3854596; 741696, 3854596; 741734, 3854379; 741759, 3854299; 741781, 3854220; 741811, 3854104; 741858, 3853961; 741870, 3853929; 741886, 3853898; 741906, 3853865; 741932, 3853833; 741976, 3853784; 742010, 3853736; 742033, 3853682; 742054, 3853628; 742075, 3853579; 742092, 3853547; 742113, 3853517; 742142, 3853481; 742183, 3853444; 742227, 3853411; 742263, 3853385; 742305, 3853361; 742316, 3853357; 742332, 3853353; 742346, 3853356; 742362, 3853362; 742371, 3853371; 742375, 3853385; 742374, 3853410; 742374, 3853450; 742374, 3853462; 742379, 3853481; 742385, 3853496; 742392, 3853507; 742401, 3853515; 742411, 3853518; 742433, 3853515; 742447, 3853508; 742463, 3853498; 742486, 3853490; 742511, 3853490; 742525, 3853492; 742539, 3853496; 742565, 3853509; 742580, 3853517; 742594, 3853520; 742605, 3853519; 742616, 3853515; 742626, 3853502; 742634, 3853485; 742643, 3853466; 742653, 3853451; 742664, 3853433; 742687, 3853414; 742700, 3853411; 742712, 3853411; 742723, 3853417; 742734, 3853429; 742742, 3853451; 742741, 3853472; 742735, 3853490; 742727, 3853511; 742719, 3853537; 742718, 3853556; 742720, 3853577; 742741, 3853616; 742753, 3853632; 742766, 3853645; 742786, 3853648; 742809, 3853648; 742820, 3853648; 742834, 3853645; 742856, 3853634; 742980, 3853487; 742994, 3853477; 743010, 3853470; 743024, 3853466; 743040, 3853463; 743058, 3853467; 743068, 3853470; 743074, 3853474; 743082, 3853492; 743087, 3853504; 743090, 3853519; 743092, 3853546; 743094, 3853569; 743097, 3853585; 743100, 3853593; 743100, 3853606; 743090, 3853656; 743091, 3853667; 743104, 3853684; 743125, 3853694; 743146, 3853691; 743171, 3853681; 743201, 3853671; 743217, 3853677; 743229, 3853688; 743247, 3853721; 743259, 3853762; 743269, 3853790; 743277, 3853849; 743300, 3853819; 743300, 3853818; 743323, 3853777; 743397, 3853668; 743403, 3852407; 743404, 3851838; 743379, 3851848; 743310, 3851856; 743246, 3851854; 743210, 3851862; 743160, 3851881; 743107, 3851862; 743071, 3851848; 743035, 3851839; 743001, 3851841; 742976, 3851860; 742953, 3851890; 742771, 3852099; 742735, 3852126; 742695, 3852156; 742663, 3852192; 742649, 3852236; 742651, 3852268; 742642, 3852300; 742625, 3852327; 742598, 3852357; 742575, 3852378; 742539, 3852388; 742505, 3852386; 742458, 3852350; 742323, 3852141; 742287, 3852122; 742251, 3852112; 742211, 3852124; 742169, 3852135; 742123, 3852135; 742080, 3852131; 742051, 3852137; 742006, 3852145; 741962, 3852148; 741932, 3852156; 741901, 3852177; 741880, 3852198; 741859, 3852205; 741829, 3852198; 741806, 3852207; 741774, 3852219; 741753, 3852232; 741730, 3852234; 741709, 3852230; 741694, 3852238; 741683, 3852257; 741666, 3852279; 741645, 3852298; 741540, 3852314; 741527, 3852333; 741521, 3852365; 741485, 3852388; 741464, 3852395; 741430, 3852405; 741413, 3852426; 741362, 3852448; 741324, 3852462; 741273, 3852494; 741240, 3852526; 741056, 3852733; 740995, 3852819; 740969, 3852874; 740948, 3852919; 740914, 3852929; 740739, 3852925; 740638, 3852914; 740536, 3852895; 740395, 3852862; 740249, 3852823; 740205, 3852807; 740165, 3852787; 740120, 3852761; 740076, 3852741; 740029, 3852725; 739996, 3852721; 739966, 3852736; 739949, 3852758; 739935, 3852794; returning to coordinates 739930, 3852832.

(ii) **Note:** Unit 3 (Map 4) follows:

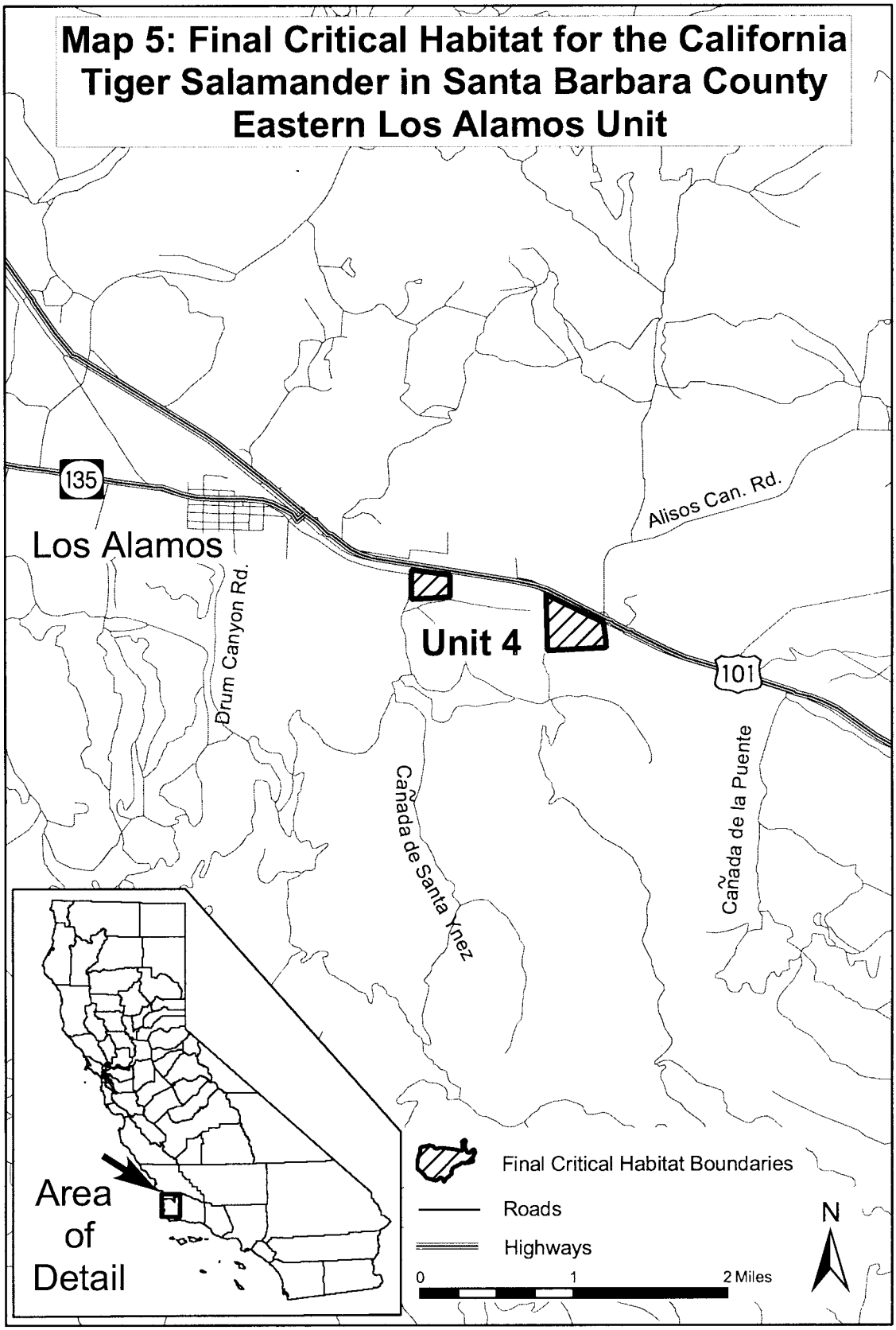


(9) Unit 4: Eastern Los Alamos Unit, Santa Barbara County, California.

(i) From USGS 1:24,000 scale quadrangle maps Los Alamos and Zaca Creek. Lands bounded by UTM Zone 10, NAD 1927 coordinates (E, N): 751549,

3847022; 751555, 3846792; 751152, 3846766; 751147, 3847077; 751215, 3847070; return to coordinates 751549, 3847022; 752562, 3846818; 752566, 3846816; 752568, 3846815; 753162, 3846522; 753190, 3846371; 753198, 3846259; 752581, 3846225; 752562, 3846811; returning to coordinates 752562, 3846818.

(ii) **Note:** Unit 4 (Map 5) follows:

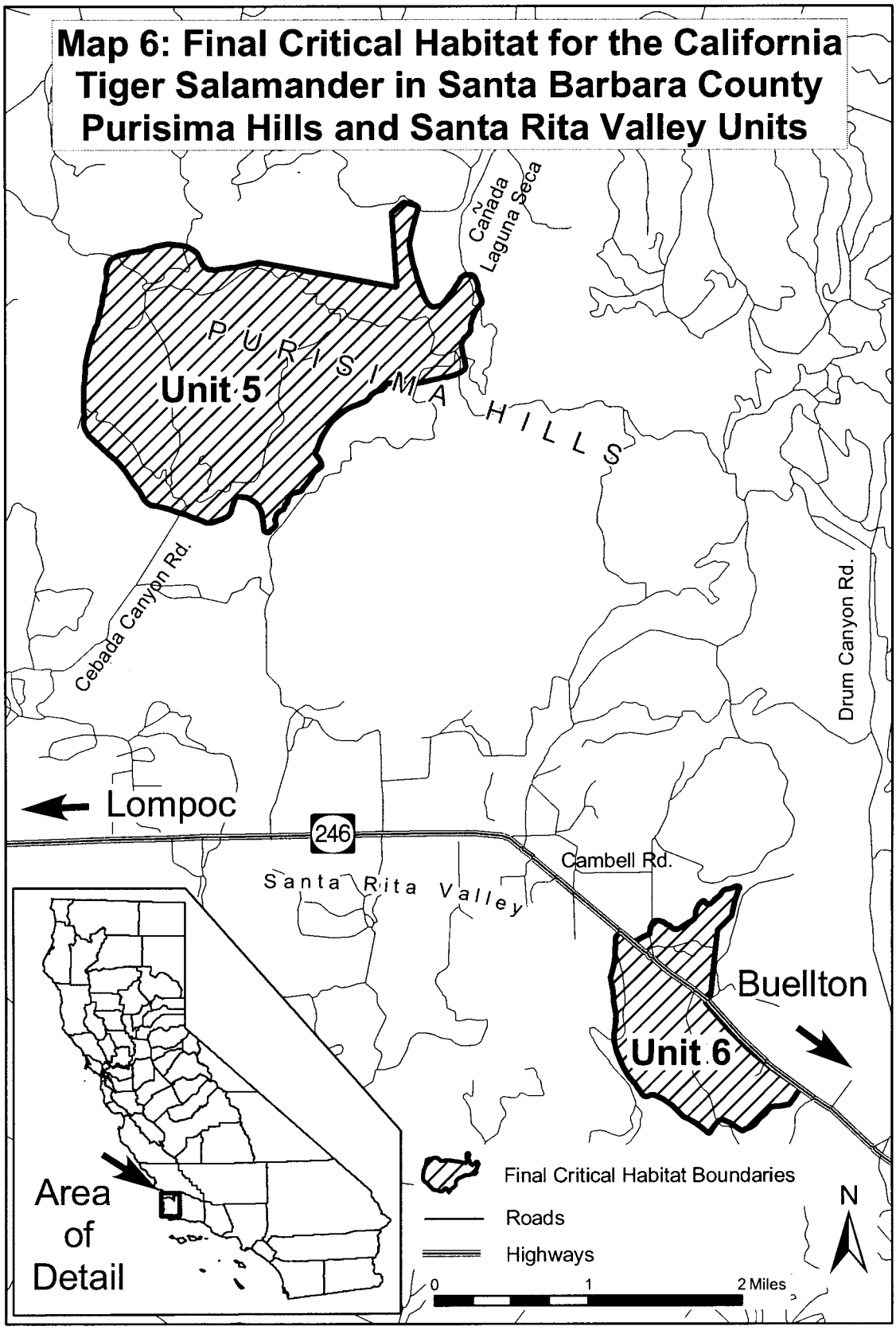

Map 5: Final Critical Habitat for the California Tiger Salamander in Santa Barbara County Eastern Los Alamos Unit
135
Los Alamos
Drum Canyon Rd.
Alisos Can. Rd.
Unit 4
101
Cañada de Santa Ynez
Cañada de la Puente
Area of Detail
Final Critical Habitat Boundaries
Roads
Highways
0
1
2 Miles
N

(10) Unit 5 (Purisima Hills) and Unit 6 (Santa Rita Valley), Santa Barbara County, California.

(i) From USGS 1:24,000 scale quadrangle maps Lompoc and Los Alamos. Lands bounded by UTM Zone 10, NAD 1927 coordinates (E, N): 740315, 3843441; 740315, 3843571; 740333, 3843694; 740344, 3843851; 740379, 3844016; 740440, 3844211; 740465, 3844252; 740500, 3844403; 740514, 3844454; 740523, 3844541; 740545, 3844615; 740543, 3844650; 740562, 3844732; 740560, 3844813; 740574, 3844876; 740605, 3844928; 740632, 3844951; 740687, 3844979; 740760, 3844996; 740805, 3845008; 740854, 3845018; 740926, 3845027; 740998, 3845045; 741062, 3845070; 741215, 3845097; 741303, 3845088; 741330, 3845084; 741406, 3845068; 741449, 3845049; 741505, 3845008; 741534, 3844944; 741565, 3844878; 741622, 3844831; 741696, 3844819; 741830, 3844848; 741927, 3844856; 742032, 3844878; 742137, 3844897; 742187, 3844900; 743020, 3844746; 743600, 3844639; 743544, 3845422; 743666, 3845536; 743782, 3845507; 743804, 3845490; 743820, 3845487; 743817, 3845472; 743789, 3845364; 743754, 3845216; 743731, 3845103; 743737, 3845037; 743766, 3844881; 743795, 3844800; 743801, 3844755; 743885, 3844535; 743914, 3844487; 743935, 3844452; 743955, 3844439; 743980, 3844433; 744015, 3844435; 744049, 3844447; 744076, 3844462; 744101, 3844484; 744191, 3844607; 744256, 3844716; 744267, 3844736; 744287, 3844751; 744316, 3844765; 744347, 3844771; 744379, 3844771; 744398, 3844763; 744416, 3844745; 744431, 3844716; 744453, 3844650; 744443, 3844611; 744459, 3844574; 744482, 3844523; 744488, 3844488; 744482, 3844462; 744449, 3844433; 744425, 3844386; 744406, 3844347; 744392, 3844304; 744379, 3844255; 744375, 3844189; 744361, 3844156; 744334, 3844132; 744306, 3844106; 744283, 3844062; 744275, 3844028; 744279, 3843987; 744291, 3843933; 744308, 3843884; 744316, 3843839; 744320, 3843801; 744303, 3843764; 744258, 3843733; 744257, 3843733; 744209, 3843711; 744131, 3843692; 744083, 3843690; 744032, 3843674; 743962, 3843661; 743896, 3843643; 743768, 3843616; 743739, 3843608; 743690, 3843610; 743673, 3843616; 743651, 3843624; 743587, 3843624; 743548, 3843624; 743519, 3843624; 743488, 3843616; 743467, 3843585; 743439, 3843558; 743414, 3843550; 743391, 3843543; 743373, 3843538; 743327, 3843503; 743319, 3843489; 743303, 3843462; 743280, 3843443; 743228, 3843421; 743222, 3843416; 743194, 3843404; 743150, 3843392; 743095, 3843367; 743037, 3843328; 742969, 3843276; 742924, 3843237; 742891, 3843194; 742856, 3843132; 742817, 3843073; 742790, 3842998; 742767, 3842937; 742745, 3842914; 742741, 3842893; 742755, 3842875; 742776, 3842844; 742796, 3842819; 742811, 3842782; 742808, 3842754; 742808, 3842756; 742806, 3842745; 742724, 3842689; 742714, 3842673; 742714, 3842654; 742699, 3842642; 742691, 3842619; 742679, 3842599; 742658, 3842574; 742619, 3842523; 742600, 3842496; 742580, 3842488; 742559, 3842481; 742528, 3842473; 742512, 3842467; 742491, 3842453; 742469, 3842436; 742460, 3842407; 742452, 3842376; 742446, 3842358; 742432, 3842352; 742423, 3842346; 742423, 3842331; 742423, 3842321; 742415, 3842300; 742401, 3842292; 742382, 3842284; 742366, 3842278; 742360, 3842263; 742347, 3842255; 742337, 3842238; 742331, 3842214; 742325, 3842195; 742322, 3842177; 742333, 3842156; 742333, 3842133; 742325, 3842113; 742308, 3842100; 742283, 3842082; 742263, 3842053; 742215, 3842063; 742205, 3842084; 742199, 3842144; 742189, 3842214; 742182, 3842267; 742162, 3842317; 742131, 3842362; 742065, 3842407; 742020, 3842428; 741952, 3842434; 741925, 3842430; 741907, 3842411; 741884, 3842343; 741859, 3842259; 741834, 3842222; 741785, 3842199; 741678, 3842164; 741618, 3842152; 741524, 3842191; 741449, 3842218; 741383, 3842245; 741322, 3842265; 741194, 3842306; 741101, 3842329; 741029, 3842343; 740984, 3842374; 740953, 3842407; 740908, 3842494; 740846, 3842572; 740805, 3842632; 740760, 3842702; 740681, 3842796; 740578, 3842885; 740374, 3843079; 740346, 3843118; 740329, 3843163; 740321, 3843192; 740323, 3843280; 740319, 3843359; returning to coordinates 740315, 3843441.

(ii) From USGS 1:24,000 scale quadrangle map Los Alamos. Lands bounded by UTM Zone 10, NAD 1927 coordinates (E, N): 745831, 3837355; 745836, 3837400; 745868, 3837517; 745882, 3837595; 745885, 3837796; 745931, 3837850; 745943, 3837841; 746054, 3837754; 746086, 3837749; 746174, 3837796; 746193, 3837805; 746210, 3837817; 746240, 3837814; 746238, 3837834; 746237, 3837848; 746238, 3837859; 746246, 3837885; 746252, 3837904; 746264, 3837925; 746270, 3837939; 746273, 3837961; 746333, 3837969; 746362, 3837961; 746389, 3837952; 746410, 3837932; 746447, 3837910; 746481, 3837886; 746510, 3837871; 746524, 3837871; 746574, 3837901; 746641, 3837941; 746671, 3837958; 746698, 3837971; 746711, 3837990; 746719, 3838016; 746722, 3838057; 746732, 3838099; 746754, 3838127; 746774, 3838153; 746800, 3838178; 746812, 3838172; 746830, 3838154; 746849, 3838139; 746872, 3838143; 746890, 3838153; 746910, 3838175; 746936, 3838195; 746973, 3838226; 747007, 3838275; 747028, 3838292; 747042, 3838295; 747065, 3838297; 747100, 3838307; 747126, 3838325; 747165, 3838333; 747192, 3838314; 747175, 3838300; 747164, 3838280; 747130, 3838159; 747094, 3838014; 746951, 3837865; 746923, 3837601; 746880, 3837223; 746875, 3837182; 746875, 3837180; 746819, 3837113; 747089, 3836795; 747166, 3836717; 747266, 3836621; 747421, 3836483; 747555, 3836383; 747819, 3836198; 747789, 3836153; 747755, 3836094; 747708, 3836034; 747619, 3836017; 747525, 3836009; 747485, 3835980; 747470, 3835953; 747470, 3835945; 747428, 3835918; 747391, 3835882; 747345, 3835822; 747298, 3835796; 747255, 3835776; 747202, 3835757; 747159, 3835786; 747080, 3835838; 747045, 3835853; 747015, 3835866; 746987, 3835870; 746960, 3835858; 746907, 3835796; 746883, 3835755; 746875, 3835741; 746860, 3835729; 746841, 3835737; 746825, 3835750; 746722, 3835836; 746666, 3835870; 746586, 3835909; 746526, 3835966; 746474, 3836020; 746369, 3836096; 746284, 3836134; 746251, 3836133; 746219, 3836119; 746195, 3836119; 746169, 3836122; 746153, 3836147; 746086, 3836247; 746015, 3836335; 745961, 3836422; 745892, 3836592; 745874, 3836696; 745868, 3836781; 745884, 3836906; 745884, 3836988; 745866, 3837121; 745866, 3837174; 745855, 3837241; 745837, 3837310; returning to coordinates 745831, 3837355.

(iii) **Note:** Units 5 and 6 (Map 6) follow:


Map 6: Final Critical Habitat for the California Tiger Salamander in Santa Barbara County Purisima Hills and Santa Rita Valley Units
Cañada Laguna Seca
PURISIMA HILLS
Unit 5
Cebada Canyon Rd.
Drum Canyon Rd.
Lompoc
246
Cambell Rd.
Santa Rita Valley
Buellton
Unit 6
Area of Detail
Final Critical Habitat Boundaries
Roads
Highways
0
1
2 Miles
N

* * * * *

Dated: November 15, 2004.

Paul Hoffman,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 04–25775 Filed 11–18–04; 1:00 pm]

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Wednesday,
November 24, 2004

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 1270, and 1271

Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 1270, and 1271

[Docket No. 1997N–484P]

Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; recordkeeping; and the establishment of a quality program. The agency is also issuing new regulations pertaining to labeling, reporting, inspections, and enforcement that will apply to manufacturers of those HCT/Ps regulated solely under the authority of the Public Health Service Act (PHS Act), and not as drugs, devices, and/or biological products. The agency's actions are intended to improve protection of the public health while keeping regulatory burden to a minimum, which in turn would encourage significant innovation.

DATES: This rule is effective May 25, 2005.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

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I. Introduction

This rule represents the culmination of FDA's efforts to establish a comprehensive new system for regulating HCT/Ps. The regulations now being issued require certain HCT/Ps to be manufactured in compliance with CGTP. The rule also contains provisions relating to establishment inspection and enforcement, as well as certain labeling and reporting requirements, which are applicable to those HCT/Ps regulated solely under the authority of section 361 of the PHS Act (42 U.S.C. 264) and the regulations in part 1271 (21 CFR part 1271), and not as drugs, devices, and/or biological products under the Federal Food, Drug, and Cosmetic Act (the act).

At this time we (FDA) are not responding to comments submitted on subparts D and E of the proposed rule relating to reproductive HCT/Ps. With two minor exceptions, the regulations in subparts D and E are not being finalized with respect to reproductive HCT/Ps described in § 1271.10 and regulated solely under section 361 of the PHS Act and the regulations in part 1271. The docket will remain open, and we ask that interested parties submit comments on communicable disease risks associated with reproductive HCT/Ps and appropriate regulation to minimize those risks (other than that stipulated in part 1271 subparts A, B, C, and F, and §§ 1271.150(c) and 1271.155 in subpart D).

A. Background

In February 1997, FDA proposed a new, comprehensive approach to the regulation of human cellular and tissue-based products (now called human cells, tissues, and cellular and tissue-based products or HCT/Ps). The agency announced its plans in two documents entitled ''Reinventing the Regulation of Human Tissue'' and ''A Proposed Approach to the Regulation of Cellular and Tissue-based Products'' (hereinafter ''proposed approach document''). FDA requested written comments on its proposed approach and, on March 17, 1997, held a public meeting to solicit information and views from the interested public (62 FR 9721, March 4, 1997).

Since that time, the agency has published two final rules and one interim final rule to implement aspects of the proposed approach. On January 19, 2001, we issued regulations to create a new, unified system for registering HCT/P establishments and for listing their HCT/Ps (registration final rule, 66 FR 5447). Part of the definition of ''human cells, tissues, or cellular or tissue-based products'' became effective on January 21, 2004. On January 27, 2004 (69 FR 3823), we issued an interim final rule to except human dura mater and human heart valve allografts from the scope of that definition until all of the tissue rules became final. On May 25, 2004, we issued regulations requiring most cell and tissue donors to be tested and screened for relevant communicable diseases (donor-eligibility final rule, 69 FR 29786).

This rulemaking was initiated with a proposed rule on January 8, 2001 (Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement (66 FR 1508) (hereinafter ''proposed rule'')). In the proposed approach document, the agency stated that it would require that cells and tissues be handled according to procedures designed to prevent contamination and to preserve tissue function and integrity. The proposed rule would require establishments that manufacture HCT/Ps to comply with CGTP, which would include, among other things, proper handling, processing, labeling, and recordkeeping procedures. In addition, the proposed regulations would require each establishment to maintain a ''quality program'' to ensure compliance with CGTP.

The proposed CGTP and other regulations would be contained in part 1271, along with provisions relating to establishment registration and donor eligibility that have previously been issued. We are now making those proposed regulations final for HCT/Ps collected on or after the effective date of this rule. We are also amending part 1270 (21 CFR part 1270), which now applies to certain HCT/Ps collected before the effective date of this rule, by modifying the definition of human tissue intended for transplantation (21 CFR 1270.3(j)) to limit its applicability to tissue collected before the effective date. We are not revoking part 1270 as previously proposed (66 FR 1508 at

1509). See section IV.B. of this document for further discussion.

Part 1271 contains six subparts. Subpart A of part 1271 sets forth scope and purpose as well as definitions. Subpart B of part 1271 contains registration procedures. Subpart C of part 1271 sets forth provisions for the screening and testing of donors to determine their eligibility. This rule puts in place three additional subparts. Subpart D of part 1271 contains the provisions on CGTP. Subpart E of part 1271 contains certain labeling and reporting requirements, and subpart F of part 1271 contains the inspection and enforcement provisions. The subparts apply as follows:

- Subparts A through D apply to all HCT/Ps, i.e., to those HCT/Ps described in § 1271.10 and regulated solely under section 361 of the PHS Act, and to those regulated as drugs, devices, and/or biological products; and
- Subparts E and F, which pertain to labeling, reporting, inspection, and enforcement, apply only to those HCT/Ps described in § 1271.10 and regulated solely under section 361 of the PHS Act. However, as previously noted in section I of this document, with the exception of two provisions (§§ 1271.150(c) and 1271.155) subparts D and E are not being implemented for reproductive HCT/Ps described in § 1271.10 and regulated solely under section 361 of the PHS Act.

The publication of this final rule completes the set of regulations that implements FDA's proposed approach to regulating HCT/Ps. We recognize that over the course of this rulemaking, inadvertent errors or inconsistencies may have been introduced into the regulations. Accordingly, we anticipate that we may need to issue technical corrections in the future.

B. Legal Authority

FDA is issuing these new regulations under the authority of section 361 of the PHS Act. Under that section, by delegation from the Surgeon General and the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. It is important to recognize that HCT/P manufacturing inevitably has interstate effects. HCT/Ps recovered in one State may be sent to another for processing, then shipped for use throughout the United States, or beyond. FDA has been involved in many recalls where HCT/Ps processed in a single establishment have been distributed in many States. In any event, intrastate transactions affecting interstate communicable disease transmission may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).)

Section 361 of the PHS Act authorizes FDA to issue regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. Certain diseases, such as those caused by the human immunodeficiency virus (HIV) and the hepatitis B and C viruses (HBV and HCV respectively), may be transmitted through the implantation, transplantation, infusion, or transfer of HCT/Ps derived from infected donors. The agency required, in another rule, that most cell and tissue donors be screened and tested for these and other relevant communicable diseases (donor-eligibility final rule, 69 FR 29786 at 29830). However, donor screening and testing, although crucial, are not sufficient to prevent the transmission of disease by HCT/Ps. Rather, each step in the manufacturing process needs to be appropriately controlled. Errors in labeling, mixups of testing records, failure to adequately clean work areas, and faulty packaging are examples of improper practices that could produce a product capable of transmitting disease to its recipient. Similarly, as noted in the proposed approach document, improper handling of an HCT/P can lead to bacterial or other pathogenic contamination of the HCT/P, or to cross-contamination between HCT/Ps, which in turn can endanger recipients. The agency has determined that the procedural provisions of this rule are necessary to ensure that the important protections created by these regulations are actually effected and are not simply empty promises. Only manufacturing conducted in accordance with established procedures can assure that HCT/Ps meet the standards in these rules. When processes are made up as the manufacturer goes along, mistakes inevitably are made. Moreover, review of procedures can be critical to determining the cause of a disease transmission. Without that analysis, it would be impossible to prevent a future occurrence, with possibly fatal consequences.

The record requirements of this rule are similarly necessary. A single donor may be the source of a large number of HCT/Ps. It may be discovered, long after the donation and transplantations have been completed, that, due to an error in processing, the donor tissue was infected and capable of spreading communicable disease. Although it might be too late to prevent infections in the recipients, it would not be too late for the recipient to obtain treatment and take steps to avoid infecting others, such as close family members. Unless adequate records were maintained, and maintained for the period of time throughout which infections may be identified, it would be impossible to identify the recipients potentially infected by the donor's HCT/Ps. This would be a critical breakdown in the prevention of disease transmission.

Moreover, a single processing error, such as an improper practice that permitted bacterial contamination of all tissue processed at a location during a limited period of time, may also have wide ranging effects. Without reporting and study of adverse events involving the transmission of communicable disease, or involving the release of HCT/Ps presenting an increased risk of such transmission, common causes of seemingly isolated incidents would never come to light. Affected HCT/Ps would continue to place patients at risk of communicable disease. Accordingly, FDA has also determined that HCT/P tracking, maintenance and retention of records, and reporting of adverse reactions and HCT/P deviations are necessary to prevent the transmission of communicable disease through HCT/Ps.

The CGTP regulations govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps. CGTP requirements are a fundamental component of FDA's risk-based approach to regulating HCT/Ps. HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in part 1271 are not regulated under the act or section 351 of the PHS Act (42 U.S.C. 262). By requiring that HCT/Ps meeting the criteria listed in § 1271.10 (361 HCT/Ps) be manufactured in compliance with CGTP, in combination with the other requirements in part 1271, the agency can ensure that 361 HCT/Ps are subject to sufficient regulatory controls to protect the public health.

HCT/Ps regulated as drugs, devices, and/or biological products, and not as 361 HCT/Ps, must be manufactured in accordance with CGTP, in addition to existing requirements. The CGTP regulations supplement the current good manufacturing practice (CGMP) and quality system (QS) regulations applicable to drugs, devices, and biological products in parts 210, 211, and 820 (21 CFR parts 210, 211, and 820). Thus, in keeping with the plan outlined in the proposed approach document, those HCT/Ps regulated as drugs, devices, and/or biological products are subject to CGMP regulations as well as to CGTP regulations. In the donor-eligibility final

rule, the agency amended the existing CGMP regulations for drugs and the QS requirements for devices to reference the testing and screening provisions of part 1271, subpart C, as well as the CGTP procedures of part 1271, subpart D.

FDA is also relying on its authority under section 361 of the PHS Act for several reporting, labeling, inspection, and enforcement provisions. Because products regulated as drugs, devices, or biological products are already subject to similar requirements, these provisions in subparts E and F would apply only to 361 HCT/Ps. Subpart E of part 1271 contains regulations on reporting and labeling pertaining to 361 HCT/Ps and is discussed in section III.D. of this document. Subpart F of part 1271 contains inspection and enforcement provisions also applicable only to 361 HCT/Ps; the relevant discussion appears in section III.E of this document.

In addition, under section 368(a) of the PHS Act (42 U.S.C. 271), any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted. For organizational defendants, fines range up to $200,000 and $500,000. Individuals and organizations also face possible alternative fines based on the amount of gain or loss. (18 U.S.C. 3559 and 3571(b) to (d)). Federal District Courts also have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. (See *Califano* v. *Yamasaki*, 442 U.S. 682, 704–05 (1979); *United States* v. *Beatrice Foods Co.*, 493 U.S. 961 (1975).)

II. Revisions to the Proposed Rule

A. Plain Language

On June 1, 1998, the Presidential Memorandum on Plain Language in Government Writing was issued in the **Federal Register** (63 FR 31885). The purpose of the plain language initiative is to create government documents that are easier to understand.

In response to this initiative, we have written the CGTP regulations in plain language. We have:

- Reorganized some regulatory sections for greater clarity, and
- Followed other plain-language conventions, such as using ''must'' instead of ''shall.''

The resulting codified language is easier to read and understand than the proposed regulation. These editorial changes are for clarity only and do not change the substance of the requirements.

B. HCT/P Definition

In the registration final rule, we discussed our decision to replace the term ''human cellular and tissue-based products'' with ''human cells, tissues, and cellular and tissue-based products'' (abbreviated ''HCT/Ps'') (66 FR 5447 at 5455). For consistency, we have made the same change in this final rule.

Also in the registration final rule, we put into place a two-part definition of HCT/P to stagger the effective dates of the registration and listing regulations for different types of HCT/Ps. We stated in the registration final rule that, when all the regulations that make up part 1271 are issued, we would revoke § 1271.3(d)(1) and renumber paragraph (d)(2) as a conforming amendment. At that time the new regulatory framework contained in part 1271 would be instituted as a whole (66 FR 5447 at 5450). We recognized that unanticipated delays in completing the rulemaking for the remainder of part 1271 could occur, and we noted that, should the rulemaking proceedings be delayed past the anticipated 2-year timeframe, we would consider whether to maintain the 2-year effective date for the HCT/Ps described in § 1271.3(d)(2) or whether to extend that date (66 FR 5447 at 5449). Since the rulemaking proceedings were delayed past the original 2-year effective date of January 21, 2003, we delayed the effective date of § 1271.3(d)(2) until January 21, 2004(68 FR 2690, January 21, 2003), on which date § 1271.3(d)(2) became effective.

On January 27, 2004, we issued an interim final rule excepting human dura mater and human heart valve allografts from the definition of HCT/P in § 1271.3(d) (69 FR 3823). We stated that, when the comprehensive framework is in place, FDA intends that human dura mater and human heart valves will be subject to it, and that FDA intends to revoke the interim rule at that time (69 FR 3823 and 3824). With the effective date of this final rule, we are revoking the interim rule and revising the language in § 1271.3(d).

C. Function and Integrity

The proposed rule contained provisions addressing our concerns about the spread of communicable disease through the use of products whose function or integrity have been impaired (66 FR 1508 at 1510). As discussed in Comment 9, we have removed from the regulations all references to function or integrity.

D. Core CGTP Requirements

In drafting this rule, we have re-evaluated each requirement of the proposed rule to ensure that it either directly prevents the introduction, transmission, or spread of communicable diseases (e.g., the requirement to store HCT/Ps at an appropriate temperature), or that it supports such a requirement (e.g., the requirement to periodically review recorded temperatures to ensure that the temperatures have been within acceptable limits). We have removed requirements where the connection to the prevention of the introduction, transmission, or spread of communicable diseases may be more attenuated.

As a result of this analysis, these final regulations are organized differently from the proposed regulations and contain fewer requirements. ''Core CGTP requirements'' are listed in § 1271.150(b); these requirements are directly related to preventing the introduction, transmission, or spread of communicable diseases. Certain requirements in subparts D and E are now limited in their applicability to these core CGTP requirements (e.g., the required records management system in § 1271.270(b) relates solely to core CGTP requirements). We have also reorganized sections within these subparts so that the core CGTP requirements appear first within a section, with supporting requirements following (e.g., § 1271.190 on facilities has been reorganized so that requirements for procedures and records, which are not core requirements, occur in paragraph (d)).

Due to the more limited nature of these final regulations, we have removed certain proposed requirements, despite their potential importance to an establishment's operations. We stress that their absence from these final regulations should not be seen as a determination that they are without value. Rather, at this time, we are issuing a more limited set of requirements than proposed. These requirements represent minimum expectations, but an establishment may decide to do more than this minimum.

E. Other Revisions

We are amending, rather than revoking, the regulations in part 1270. See section IV of this document for further discussion.

We have made changes from the proposal throughout the regulations to be more clear; to link the regulations more closely to preventing the transmission of communicable diseases,

as discussed in section II.D of this document; and in response to comments discussed in section III of this document. These revisions include:

- Adding § 1271.145, which requires establishments to manufacture HCT/Ps in a way that prevents the introduction, transmission, or spread of communicable diseases;
- Revising the definitions for ''adverse reaction,'' ''available for distribution,'' ''complaint,'' ''distribution,'' ''product deviation,'' ''processing,'' ''quality audit,'' and ''quality program'';
- Adding § 1271.215, which requires establishments to recover HCT/Ps in a way that does not cause contamination or cross-contamination during recovery, or otherwise increase the risk of the introduction, transmission, or spread of communicable disease through the use of the HCT/P;
- Deleting proposed § 1271.220(b) *Processing material* and the definition of that term in proposed § 1271.3(hh);
- Adding paragraph (b) to § 1271.265;
- Adding language in § 1271.420 to facilitate rapid admissibility decisions for imported HCT/Ps that meet requirements, and to except cells and tissues from a sexually intimate partner, and peripheral blood stem/progenitor cells from the requirement for an admissibility decision; and
- Adding pertinent references to ''preventing the introduction, transmission, or spread of communicable diseases,'' where it is useful to explain the purposes or scope of a requirement.

We have also made technical amendments to §§ 1271.10(a)(3) and 1271.22(b) and (c). Section 1271.10(a)(3) is revised by adding ''water'' and ''crystalloids'' to the exceptions because, as with sterilizing, preserving and storage agents, these substances generally do not raise safety concerns. Water or crystalloids (e.g., saline solution, Ringer's lactate solution, or 5% dextrose in water) are typically added to lyophilized HCT/Ps by the user to reconstitute the HCT/P. We have also revised § 1271.10(a)(3) by replacing ''the combination of the cell or tissue component with a drug or device'' with ''the combination of cells or tissues with an article.'' We found that establishments were confused by the reference to drugs and devices in this context, and did not understand how to evaluate the drug or device function of the additive in the context of the product. By substituting the term ''article,'' we eliminate this ambiguity, we focus more directly on the risks presented by such additives, and we therefore make this provision more consistent with the risk-based approach supporting the balance of the rule.

Section 1271.22 is revised by updating the mailcodes in paragraphs (b)(i) and (c)(i), by removing paragraph (b)(iv) since the Fax Information System is no longer in service, and by providing information for the electronic submission of Form FDA 3356.

Section 1271.45(a) is amended by adding that other CGTP requirements are set out in subpart D of part 1271. This statement clarifies that subparts C and D together constitute CGTP requirements.

III. Comments on the Proposed Rule and FDA's Responses

We received 47 comments on the proposed rule. Several comments raised issues that were addressed in the registration final rule (e.g., determining the regulatory categorization of HCT/Ps). Responses to these comments may be found in the registration final rule at Comment 7 (66 FR 5447 at 5451), Comment 8 (66 FR 5447 at 5452), and Comment 30 (66 FR 5447 at 5459). Other comments on this rule raised issues relating to the donor-eligibility rule; we addressed these comments in the donor-eligibility final rule at Comment 25 (69 FR 29786 at 29796), Comment 32 (69 FR 29786 at 29799), Comment 48 (69 FR 29786 at 29806), Comment 59 (69 FR 29786 at 29809), and in section III.D.3 (69 FR 29786 at 29797).

A. General

1. General Comments

(Comment 1) Numerous comments supported the proposed rule. These comments called the rule well written and organized, easy to understand, comprehensive, and reasonable. One comment appreciated the philosophy we adopted in defining objectives rather than specific methodologies. Another comment stated that the formulation of the proposed rule and the development of the entire regulatory framework were an enormous undertaking of great importance and timeliness.

(Response) We appreciate these supportive comments. We agree with those comments recognizing both the importance of this rule and the fact that it represents the culmination of our efforts to develop a comprehensive new system of regulation for HCT/Ps.

We also note that most of the comments we received on this rule were helpful and well organized. For example, many comments were arranged by section number of the proposed regulation and contained specific suggestions on how to revise each section, often including new language. We appreciate the care with which these comments were prepared.

(Comment 2) Some comments stated general opposition to the proposed rule. One comment stated that tissue banks are self-regulating and that the rules are unnecessary. This comment further asserted that smaller tissue banks have not been informed and have been ignored, while we worked only with large organizations.

(Response) We recognize that some comments oppose the proposed rule as a general matter and do not consider the new regulations necessary or beneficial. We disagree with those comments. We also disagree with the statement that, in developing these rules, we have consulted only large professional organizations and have ignored the concerns of small banks or failed to inform them of our rulemaking. Even before this rulemaking began, we took pains to make our intentions clear to all interested parties by issuing notices and rulemakings in the **Federal Register**, which is accessible to both large and small organizations. We have held several public meetings on issues affecting the rulemaking that were open to all interested parties. We also prepared an analysis of the impact of the rulemaking on small entities in the proposed rule (66 FR 1508 at 1545). Moreover, this final rule incorporates many changes made in response to comments from a range of interested parties, including many small entities. We also will be issuing a small entity compliance guide, which will assist small entities in complying with part 1271.

(Comment 3) Several comments compared the proposed rule to industry standards. Three comments complimented us for the proposed rule's consistency with current good industry practice. In contrast, one comment argued that the proposed rule offered little additional benefit over industry standards currently in place. One comment asserted that the rule is reasonable to the extent it mirrors good manufacturing practice (GMP)/QS regulations for in vitro diagnostics and current bloodborne pathogen guidelines, but that many provisions are duplicative of the regulations and guidelines in place and create another layer of unnecessary recordkeeping. This comment stated that the rule goes beyond its original intent and places an undue regulatory burden, which would bring a halt to innovative activities.

(Response) The proposed requirements were based on current good industry practice and were intended to address what we consider to

be important minimum criteria for the manufacture of HCT/Ps in a manner that effectively reduces the risk of communicable disease transmission. In developing the proposed CGTP regulations, we reviewed several sets of industry standards (66 FR 1508 at 1511). These comments indicate that we were successful in reflecting current good practices. We note that, to the extent that industry standards are consistent with and at least as stringent as CGTP requirements and are appropriate for the operations conducted, an establishment may adopt industry's standard procedures as a way of complying with these regulations (§ 1271.180(d)). However, we decline to mandate compliance with the standards of a particular professional organization. Industry associations are welcome to submit their standards to the agency for potential adoption as guidance subject to public comment. (See 21 CFR 10.115.)

We disagree that these regulations require unnecessary recordkeeping or create an undue regulatory burden. In this final rule, we have made numerous changes to the regulatory provisions in response to comments; many of these changes will have the effect of reducing the regulatory burden from that originally proposed while still addressing communicable disease risks.

With respect to the comment on duplicative requirements applicable to HCT/Ps regulated as devices, drugs, and/or biological products, we note that § 1271.150(d) states that CGTP and CGMP regulations in parts 210 and 211 and the QS regulations in part 820 supplement each other unless the regulations explicitly provide otherwise. In the event of a conflict between applicable requirements, the regulations more specifically applicable to the product will supersede the more general requirements. FDA believes that, in the event of such a conflict, the more specifically applicable regulation would be found in part 1271. It is unnecessary to maintain two sets of records to indicate compliance with both CGTP and CGMP or QS requirements; a single set of records is adequate.

(Comment 4) Several comments requested that these regulations be phased in over time. Two comments requested a grace period of 1 to 2 years; one comment requested a 2-year implementation period; and another comment requested an extension of the compliance deadline to 1 year after publication.

(Response) We understand the request for a long implementation period. However, recent reports of bacterial infections in patients who received HCT/Ps support the implementation of the CGTP requirements as soon as possible. (Ref. 1) The effective date of the CGTP final rule will coincide with the effective date of the previously issued donor eligibility requirements. We believe that this will provide an adequate amount of time to comply with the requirements in part 1271.

(Comment 5) Two comments opposed the retrospective application of any regulation or guidance to tissue recovered before its issuance, because tissue may have a shelf life of up to 5 years. The comments suggested that the final rule should apply to HCT/Ps recovered after the effective date, and that for tissues recovered before the effective date of the final rule, the regulations in part 1270 would continue to apply.

(Response) We agree that the final rule will apply to HCT/Ps recovered on or after the rule's effective date. Cells and tissue recovered before that date are subject to the regulations in effect at the time of recovery. The regulations in part 1270 are being amended in this rulemaking so that those regulations will continue to apply only to human tissue for transplantation recovered before the effective date of this rule. See section IV.B of this document for further discussion.

(Comment 6) One comment asserted that the regulations should cover the procurement and storage of human organs for transplant, reproductive cells (sperm and ova), and the storage of human milk.

(Response) Part 1271 does not apply to human organs or to human milk. Subparts D and E are not being implemented with respect to reproductive HCT/Ps, except for §§ 1271.150(c) and 1271.155.

(Comment 7) Several comments objected to the terms ''manufacture'' and ''product'' as inappropriate for use with respect to donated human tissue. One comment asserted that corneas are recovered and evaluated, not manufactured. Some comments suggested substitute terminology: e.g., ''donor program'' or ''tissue service organization'' instead of ''manufacturer''; ''handle'' instead of ''manufacture''; and ''human cellular and tissue-based material'' instead of ''product.'' One comment asserted that, because the terminology used in the rule does not correlate with eye bank practices, it was difficult to determine which sections apply to eye banking; this comment cited the additional terms ''process,'' ''processing,'' ''processing material,'' ''validation,'' and ''verification.''

(Response) In the registration final rule, we changed the term ''human cellular or tissue-based product'' to ''human cells, tissues, and cellular and tissue-based products,'' or ''HCT/Ps.'' We made this change in response to comments that opposed calling donated tissue a ''product.'' In that final rule, we noted that we needed a term broad enough to cover both cells and tissues, and one that would include within its scope such diverse articles as unprocessed tissue, highly processed cells, and tissues that are combined with certain drugs or devices (66 FR 5447 at 5455). We believe the term ''HCT/P'' addresses the concerns expressed in the comments, and we will use that term in these regulations.

In the registration final rule, we also considered substituting a different term for ''manufacture,'' in response to similar comments, but were unable to find a satisfactory replacement. Among other terms, we considered ''handling,'' but rejected it as too limited in scope. Thus, we have continued to use the word ''manufacture'' as an umbrella term to capture the many different actions that HCT/P establishments might take in preparing HCT/Ps for use (66 FR 5447 at 5455).

Many different types of establishments are involved in the recovery, screening, testing, processing, storage, labeling, packaging, and distribution related to HCT/Ps. Some of these may accurately be called tissue service organizations, donor programs, or tissue procurement organizations, and may certainly continue to call themselves by these names. However, these terms are too limited to cover those establishments that perform other manufacturing functions, and for that reason we decline to adopt any of these suggested terms in this regulation. We note that, although these rules at times refer to ''manufacturers,'' the more frequently used term is ''establishment.''

With respect to the comment on the applicability of these regulations to eye banks, we discuss the applicability of specific sections throughout this final rule. We note that each establishment is required to comply only with those requirements that apply to the activities in which it engages. We are working, with input from industry and others, to develop guidances specific to different types of HCT/Ps; this effort is intended to help establishments comply with these CGTP requirements to control the risk of communicable disease transmission.

(Comment 8) Comments from eye banking organizations stated that eye and cornea banking differ from other tissue banking.

(Response) We acknowledge that, in some ways, eye banking differs from other tissue banking. However, since 1993, ocular tissue has been regulated under the regulatory model for all human tissues for transplantation. Eye banks are similar to tissue banks in that they recover, process (although minimally), store, label, package, or distribute human tissue, screen and test the tissue donor, report adverse reactions, and track tissue. We have intentionally crafted broad CGTP regulations for flexibility with the expectation that each bank will specify its own operating procedures. In addition, we have stated that an establishment need only comply with those requirements that are applicable to the operations in which it engages.

2. Function and Integrity

The proposed CGTP requirements were intended, in part, to prevent the introduction, transmission, or spread of communicable disease by helping to ensure that the function and integrity of HCT/Ps are not impaired through improper manufacturing (proposed § 1271.150(a); see 66 FR 1508 at 1510). Many of the provisions of the proposed rule contained requirements intended to help ensure HCT/P function and integrity. For example, proposed § 1271.260 would require an establishment to control its storage areas to prevent conditions that may adversely affect function or integrity.

(Comment 9) Approximately nine comments objected to the proposed rule's provisions on function and integrity. Some of these comments criticized our justification for these provisions as weak or theoretical; these comments questioned whether the impairment of an HCT/P's function and integrity actually increases the risk of disease transmission. Other comments argued that section 361 of the PHS Act cannot be interpreted to cover an HCT/P's function and integrity. Several comments requested that the phrase be defined or deleted.

Several comments expressed concern that the provisions on function and integrity could be interpreted to mean that an establishment assess each HCT/P's function and integrity. These comments agreed generally with the concept of ensuring function and integrity, which they described as ensuring that an HCT/P is ''fit for use,'' but asked the agency to clarify the relationship between the concept and a risk-based system.

Most comments on the general issue of function and integrity also objected to specific sections of the proposed rule where that term appears. These comments requested the deletion of, or a substitution for, the phrase ''function and integrity,'' as well as related terms.

(Response) To increase clarity, and because of the confusion expressed by comments about the term ''function and integrity,'' we have removed from the regulations all references to function or integrity. For the same reason, we have also removed references to the related terms, ''deterioration'' and ''adverse effect.''

To avoid repetition throughout this document, comment summaries do not contain references to function and integrity (or related terms), where we received comments on that issue. Moreover, references to function and integrity, deterioration, and adverse effect, have been removed from summaries of the provisions proposed in the proposed rule. References to function and integrity have been removed from discussions of the following proposed provisions: §§ 1271.3(bb) and (kk), 1271.160, 1271.200, 1271.210, 1271.220, 1271.260, 1271.265, 1271.350, and 1271.420.

B. Definitions (§ 1271.3)

We have grouped all definitions pertinent to part 1271 in a single definitions section (§ 1271.3), among the general provisions of subpart A. The proposed rule contained proposed definitions from § 1271.3(ff) through (tt); these have been renumbered from § 1271.3(y) through (ll). We have also reordered the definitions to maintain some alphabetical order, and they are discussed according to their new order.

We have revised § 1271.3(d) by deleting paragraph (d)(1), as it is no longer applicable with the effective date of this rulemaking. We have added the terms ''repair'' and ''reconstruction'' to the definition of ''homologous use'' at § 1271.3(c) (the registration final rule, 66 FR 5447 at 5467), to provide a more complete and accurate description of the definition.

1. Adverse Reaction (§ 1271.3(y))

The proposed rule would define ''adverse reaction'' as a noxious and unintended response to any HCT/P for which there is a reasonable possibility that the response may have been caused by the product (i.e., the relationship cannot be ruled out) (66 FR 1508 at 1520). Adverse reaction reporting requirements are set out in proposed § 1271.350(a).

(Comment 10) Several comments argued that the proposed definition of ''adverse reaction'' is too broad. One comment asserted that a transplant recipient could experience a reaction to a substance in a tissue even though the manufacturer followed CGTP requirements. One comment suggested changing ''reasonable possibility'' to ''reasonable probability.''

(Response) The definition of ''adverse reaction'' is intended to capture those situations that may indicate a problem with an HCT/P and that a manufacturer should therefore investigate. A noxious and unintended response to a substance in an HCT/P would meet the definition of ''adverse reaction,'' and an establishment should evaluate the situation.

The receipt of adverse reaction reports enables us to evaluate potential relationships between reports. For example, if several separate establishments reported that a recipient of tissue that the establishments made available for distribution developed a wound infection with *Clostridium* sp., FDA might determine that a single establishment recovered or processed all of those tissues. An FDA investigation would be initiated.

It is important to note that not all adverse reactions are required to be investigated and reported. Section 1271.350(a) sets out those situations in which an establishment must make an adverse reaction report to us. An investigation is required when an adverse reaction involves a communicable disease. A report is required when such an adverse reaction is fatal or life-threatening; results in permanent impairment or damage; or necessitates medical or surgical intervention. The criteria set out in § 1271.350(a) limit the scope of the adverse reaction reporting requirement. As discussed in the preamble to the proposed rule (66 FR 1508 at 1520), this approach, and the definition of adverse reaction, are consistent with other rules we are developing and with international standards (See, e.g., ''International Conference on Harmonisation; Guideline on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting; Availability'' (ICH guideline), 60 FR 11284, March 1, 1995).

We decline to replace the word ''possibility'' with the suggested term, ''probability.'' We interpret ''reasonable possibility'' to mean that there is a possible causal relationship between an adverse experience and an HCT/P; ''there are facts (evidence) or arguments to suggest a causal relationship.'' (ICH guidance, 60 FR 11284 at 11286).

(Comment 11) One comment questioned the phrase ''the relationship cannot be ruled out.'' This comment noted that there may be multiple possible causes of a patient's problems,

and that in some instances it may be unlikely that the HCT/P is responsible.

(Response) We have removed the phrase ''the relationship cannot be ruled out'' from the definition of ''adverse reaction.'' On further examination, we believe it is not helpful in explaining what is meant by ''reasonable possibility.'' We recognize that there may be situations in which there are multiple possible causes of a patient's problem. Nevertheless, if one of the reasonable possibilities is that the HCT/P caused the problem, then this would meet the definition of ''adverse reaction.'' This would include situations in which the relationship between the response and the HCT/P is ''unlikely'' but nevertheless possible.

2. Available for Distribution (§ 1271.3(z))

The proposed regulations in § 1271.3(ff) would define ''available for distribution'' to mean that an HCT/P has been determined to meet all release specifications and to be suitable for distribution.

(Comment 12) One comment suggested this definition should be harmonized with the final rule on biologic product deviations (65 FR 66621 at 66634, November 7, 2000; 21 CFR 600.14) to clarify that reporting product deviations is only necessary after an HCT/P has left control of the establishment (i.e., has been distributed).

(Response) We agree that, under § 1271.350(b), you are required to report an HCT/P deviation only when the HCT/P has been distributed. However, we disagree that there is any need to modify the definition of ''available for distribution'' as requested by the comment. The phrase ''available for distribution'' does not appear in § 1271.350(b). We have, however, removed the words ''and to be suitable for distribution'' from the definition of ''available for distribution.'' As defined in the final rule, an HCT/P is ''available for distribution'' if it has been determined to meet all release criteria.

We discuss the definition of ''distribution'' in Comment 16.

3. Complaint (§ 1271.3(aa))

Proposed § 1271.3(ii) would define ''complaint'' as any written, oral, or electronic communication that alleges that an HCT/P has transmitted or may have transmitted a communicable disease; or any other problem with an HCT/P that could result from the failure to comply with CGTP (66 FR 1508 at 1520).

(Comment 13) One comment stated that the definition is vague and would leave eye banks open to baseless accusations by recipients, family members, or physicians for graft failure that may have been due to other causes. According to this comment, eye banks should be given an opportunity to filter out unfounded complaints.

(Response) We have revised the definition to specify that information must relate to the potential for transmission of communicable disease, such as the failure to comply with current good tissue practice (which would include the donor eligibility regulations). However, we note that a complaint may come from any source and may be a written, oral, or electronic communication. Section 1271.320 requires each establishment to have procedures in place to evaluate complaints that relate to core CGTP requirements and to determine whether investigation is necessary.

(Comment 14) Several comments noted their belief that the proposed requirements on complaints would apply only to HCT/Ps that have been released to distribution.

(Response) We agree with these comments and revised the definition to apply to distributed HCT/Ps only.

(Comment 15) Two comments requested the deletion of proposed § 1271.3(ii)(3), which covered any other problem with an HCT/P that could result from the failure to comply with CGTP. Two other comments suggested that we revise proposed § 1271.3(ii)(3) to refer to deficiencies related to the identity, quality, durability, reliability, safety, or performance of a product after it is released for distribution. A third comment recommended that paragraph (ii)(3) be deleted or clarified to indicate its application to tissues released to distribution.

(Response) We decline to delete proposed § 1271.3(ii)(3), which has been renumbered as § 1271.3(aa)(2). As previously noted, we intend the requirements with respect to complaints to apply to HCT/Ps that have been distributed. It is necessary for all establishments to have in place a system to handle communications about problems with its distributed HCT/Ps. Some problems may be traced to a failure to comply with CGTP, which could lead to additional problems that increase the risk of communicable disease transmission if not corrected. Deleting proposed § 1271.3(ii)(3) would unduly narrow the scope of the definition, allowing establishments to ignore important communications about their products. (However, we note that, as discussed in Comment 13, we have specified that information under this paragraph must relate to the potential for transmission of communicable disease.)

4. Distribution (§ 1271.3(bb))

We proposed to define ''distribution'' in § 1271.3(jj) as any conveyance or shipment of HCT/Ps (including importation and exportation), whether or not such conveyance or shipment is entirely intrastate and whether or not possession of the product is taken. We originally described our intended definition of ''distribution'' in the preamble to the registration proposed rule (63 FR 26744 at 26750), and we responded to several comments on ''distribution'' in the registration final rule (66 FR 5447 at 5456).

(Comment 16) One comment asserted that the definition of distribution in the proposed rule is inconsistent with the definition in the registration final rule. The comment pointed out that, in the preamble to the registration final rule, we agreed that an entity that does not take possession of HCT/Ps is not distributing them for the purposes of this rule.

(Response) The proposed rule, which contained the proposed codified definition of ''distribution,'' preceded the registration final rule, in which we indicated we would make changes to the proposed definition. We are now making the change to the definition that we discussed in the registration final rule; i.e., we have removed the phrase ''whether or not possession is taken'' from the definition and replaced it with ''If an entity does not take physical possession of an HCT/P that entity is not considered a distributor.''

(Comment 17) One comment requested that we clarify that intracompany transfers of HCT/Ps are not included within the definition of ''distribution,'' consistent with FDA's policy with respect to other medical products.

(Response) In response to this comment, we have modified the definition of ''distribution'' to mean any conveyance or shipment of an HCT/P ''that has been determined to meet all release criteria.'' This change is intended to make clear that the shipment of an HCT/P before it is ready for release would not be considered distribution (e.g., the movement of an HCT/P from a recovering establishment to a processing establishment). This sort of predistribution shipment might also take place between establishments that are part of the same company. On the other hand, not all intracompany shipments are appropriately excepted from the definition of ''distribution.'' For example, releasing an HCT/P from a collection/processing facility to an

operating room in the same facility would be considered distribution.

5. Establish and Maintain (§ 1271.3(cc))

Proposed § 1271.3(ll) would define ''establish and maintain'' as define, document (in writing or electronically), and implement, then follow, review, and, as needed, revise on an ongoing basis.

We received no comments on the proposed definition of ''establish and maintain.''

6. HCT/P Deviation (§ 1271.3(dd))

Proposed § 1271.3(kk) would define ''product deviation'' as an event that represents a deviation from CGTP, applicable standards, or established specifications; or an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease agent or disease from an HCT/P to a recipient, or may lead to product contamination.

In response to comments on the term ''product,'' we have changed the defined term from ''product deviation'' to ''HCT/P deviation'' (see 66 FR 5447 at 5455). We have also narrowed the definition of HCT/P deviation by revising the phrase ''a deviation from current good tissue practice, applicable standards, or established specifications'' to read ''a deviation from applicable regulations in this part or from applicable standards or established specifications that may relate to the prevention of communicable disease transmission or to the prevention of HCT/P contamination.''

Proposed § 1271.350(b) would require you to report those HCT/P deviations that could reasonably be expected to lead to a reportable adverse reaction.

(Comment 18) One comment suggested that we use the term ''process deviation'' instead of ''product deviation,'' because the definition refers to an event rather than to a deviation in the HCT/P.

(Response) We decline to make the suggested change because to do so could exclude problems that occur in areas of manufacture other than ''processing,'' such as recovery and storage, and would therefore be narrower than ''HCT/P deviation.'' Moreover, the term ''process deviation'' might introduce inconsistency with our reporting requirements in § 600.14 (21 CFR 600.14) for biological products other than blood and blood components. Establishments that manufacture HCT/Ps regulated under section 351 of the PHS Act will report under § 600.14. Establishments that manufacture HCT/Ps regulated as drugs or devices under the act will make any reports under drug and device reporting provisions.

(Comment 19) One comment noted that there are no established specifications for corneas, although there are proxy indicators (e.g., cell counts and cell morphology) that can be taken into account when evaluating tissue, and that outcomes may be dependent upon factors beyond an eye bank's control.

(Response) We understand that an eye bank might not set specifications for corneas. However, we expect that an establishment will generally set out acceptable criteria for its HCT/Ps in its standard operating procedures. These criteria may relate to such factors as storage temperature, and although not considered specifications by the establishment, they serve much the same role. Since storage temperature may relate to the prevention of communicable disease transmission or HCT/P contamination, a deviation from these criteria would be considered an HCT/P deviation You must review the deviation to determine if it must be reported under § 1271.350(b).

7. Importer of Record (§ 1271.3(ee))

Proposed § 1271.3(tt) would define ''importer of record'' as ''the person, establishment, or its representative responsible for making entry of imported goods in accordance with all laws affecting such importation.'' (66 FR 1508 at 1552).

We received no comments on the proposed definition of ''importer of record.''

8. Processing (§ 1271.3(ff))

Processing is one of the activities listed in the definition of ''manufacture'' in § 1271.3(e). The proposed rule would define ''processing'' in § 1271.3(mm) as any activity performed on an HCT/P other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution. Processing would include, but not be limited to, preparation, sterilization, steps to inactivate and remove adventitious agents, preservation for storage, and removal from storage. We have added to the definition ''testing for microorganisms'' because this activity may occur at this stage of manufacturing.

(Comment 20) One comment requested clarification of the terms ''process'' and ''processing'' as those terms are used in proposed §§ 1271.220 (process controls) and 1271.225 (process changes).

(Response) We believe that ''process'' is a generally understood term; one accepted definition of ''process'' is a ''set of interrelated or interacting activities which transfers inputs into outputs'' (International Standards Organization (ISO) 9000:2000, 3.4.1). In the context of this final rule, the set of processing activities that an establishment performs on an HCT/P would be considered a ''process.'' We consider the proposed definition of ''processing'' to be sufficiently clear and have made no substantive changes to it.

(Comment 21) One comment from an eye bank requested clarification of ''preparation,'' ''preservation for storage,'' and ''removal from storage.'' The comment noted that corneas are stored in media to maintain viability but are not preserved for long-term storage.

(Response) We believe that these terms are generally understood; however, not all of them may be applicable to eye banks. We agree that corneas are usually not preserved for long-term storage, but nevertheless, they are preserved in a corneal storage media, even for short-term storage.

Examples of corneal processing may include gross and microscopic examination of the cornea, microbiological culture of the rim, preservation in a corneal storage media, and placement into and removal from the refrigerator.

9. Processing Material

The proposed rule would define ''processing material'' in § 1271.3(hh) as any material or substance that is used in, or to facilitate, processing, but which is not intended by the manufacturer to be included in the HCT/P when it is made available for distribution.

We have deleted the relevant provision on processing material, in proposed § 1271.220(b), and as a result are also deleting this definition.

10. Quality Audit (§ 1271.3(gg))

We proposed to define ''quality audit'' in § 1271.3(nn) as a documented, independent inspection and review of an establishment's activities, including manufacturing and tracking, performed according to procedures, to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.

We have revised the definition of quality audit to mean a documented, independent inspection and review of an establishment's activities related to core CGTP requirements. The definition further states that the purpose of a quality audit is to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.

(Comment 22) One comment recommended that we define ''independent'' or insert a reference to proposed § 1271.160(d)(2), which would require that a quality audit be performed by an individual who does not have direct responsibility for the processes being audited. Another comment asked us to clarify ''independent inspection'' and asked whether an employee could perform the independent inspection. A third comment asked whether an outside accreditation process could constitute an independent review.

(Response) We do not believe it is necessary to define ''independent.'' We consider an inspection and review by an individual who does not have direct responsibility for the processes being audited to be ''independent.'' This individual could be someone outside the firm, or could be an individual within the firm who does not have direct responsibility for the matters being audited. If an accreditation process is equivalent to an internal quality audit, it would be acceptable. We decline to add a reference to the quality audit provision of § 1271.160, which has been revised.

11. Quality Program (§ 1271.3(hh))

We proposed to define ''quality program'' in § 1271.3(oo) as an organization's comprehensive system for manufacturing and tracking HCT/Ps. As defined, the program would include preventing, detecting, and correcting deficiencies that may lead to circumstances that increase the risk of introduction, transmission, or spread of communicable diseases.

We have revised the definition of ''quality program'' for clarity. The definition now states, in part, that a quality program is designed to prevent, detect, and correct deficiencies that may lead to circumstances that increase the risk of introduction, transmission, or spread of communicable diseases.

(Comment 23) One comment endorsed the concept of a quality program but noted that the preamble referred to an organization's ''method,'' while the proposed definition used the term ''system for manufacturing.'' The comment suggested that we change the codified definition to reflect the preamble.

(Response) We decline to make the suggested change; rather, we note that it would have been clearer if we had referred in the preamble to a ''system'' rather than to a ''method.'' As stated in the preamble to the proposed rule (66 FR 1508 at 1513), we use the term ''quality program'' to refer to the set of activities, including management review, training, audits, and corrective and preventive actions, that represent a commitment on the part of an establishment's management to the quality of its products. Whether this set of activities is regarded as a part of manufacture or as a separate system for overseeing manufacture, as preferred by the comment, is not material.

12. Recovery (§ 1271.3(ii))

Proposed § 1271.3(pp) would define ''recovery'' as the ''process of obtaining from a donor cells or tissues that are intended for use in human implantation, transplantation, infusion, or transfer.'' (66 FR 1508 at 1551 and 1552).

(Comment 24) One comment suggested rewording the definition of ''recovery'' to avoid referring to recovery as a process.

(Response) We agree with this comment. The word ''process'' in the definition of ''recovery'' could be confused with the definition of ''processing'' in proposed § 1271.3(mm), which does not include recovery. The definition now reads: Recovery means obtaining from a donor cells or tissues that are intended for use in human implantation, transplantation, infusion, or transfer.

13. Storage (§ 1271.3(jj))

Storage is one of the activities listed in the definition of manufacture in § 1271.3(e). We proposed to define ''storage'' in § 1271.3(qq) as holding HCT/Ps for future processing and/or distribution.

(Comment 25) One comment recommended that we clarify that the definition does not refer only to finished HCT/Ps ready for shipment and suggested that the definition refer also to ''materials.''

(Response) Although we agree that the term ''storage'' does not apply only to finished HCT/Ps, but to HCT/Ps at any stage of processing, we do not consider a revision of the definition to be necessary. The term HCT/P encompasses HCT/Ps at any stage of manufacture, from recovery to distribution (66 FR 5447 at 5448). Moreover, the definition of ''storage'' refers to ''future processing,'' which indicates that the definition applies not only to finished products but also to cells or tissues that may be subject to future processing.

14. Validation (§ 1271.3(kk))

Proposed § 1271.3(rr) would define ''validation'' as confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. The definition went on to define validation of a process, or ''process validation,'' as establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

(Comment 26) One comment requested that we harmonize the proposed definition with that of the International Conference on Harmonisation (ICH). The comment suggested that the new definition read:

> A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting predetermined acceptance criteria.

(Response) We decline to make this change. Harmonization of the two definitions is unnecessary, because the proposed definition is consistent with the language suggested by the comment. The proposed definition is preferable, however, because it explains in more specific terms what is expected (e.g., ''confirmation by examination''; ''provision of objective evidence''). In addition, the proposed definition is consistent with the ISO 9000:2000 definition of validation (Quality management system—Fundamentals and vocabulary).

(Comment 27) Two comments questioned the use of the term ''validation'' throughout the proposed rule. These comments cited industry standards that require a level of review tailored to the type of processing used for a particular tissue (e.g., validation of certain shipping containers versus verification of other aspects of processing). The comments requested clarification that compliance with these standards would be deemed compliance with the rule's validation requirements.

(Response) Where the appropriate action depends on the type of tissue or processing, the rule provides establishments with the flexibility to determine whether verification or validation is appropriate (e.g., §§ 1271.210(c) and 1271.225). Verification activities may be sufficient for certain processes if the results can be adequately determined through inspection and testing methods. When full and complete verification cannot be achieved, the process must be validated. The manufacturer should have the requisite knowledge of the processes and operations conducted at its facility to determine which actions are needed.

FDA cannot make a determination that compliance with professional standards ensures compliance with the validation requirements of this rule. Each establishment will need to assess its operations to make sure the applicable requirements of the CGTP regulation are met. We encourage

professional organizations and others to submit drafts of proposed guidance in this area for FDA to consider for possible adoption.

15. Verification (§ 1271.3(nn))

Proposed § 1271.3(ss) would define ''verification'' as ''confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.'' (66 FR 1508 at 1552).

We received no comments on the proposed definition of ''verification, '' and it is unchanged.

C. Part 1271, Subpart D—Current Good Tissue Practice

Part 1271, subpart D, sets forth CGTP requirements. We have added, in § 1271.145, an explicit statement of the basic requirement that underpins all of the provisions of this subpart. Section 1271.145 states that you must recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in a way that prevents the introduction, transmission, or spread of communicable diseases.

1. Current Good Tissue Practice Requirements (§ 1271.150)

General (§ 1271.150(a))

Proposed § 1271.150(a) states in part that the CGTP requirements are intended to prevent the introduction, transmission, or spread of communicable disease through the use of HCT/Ps by helping to ensure that they do not contain communicable disease agents and that they do not become contaminated during manufacturing. We have revised this sentence for clarity, have added the phrase ''that they are not contaminated,'' and have included the statement that ''you must follow CGTP requirements.''

We have also added to § 1271.150(a) the statement that communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy (TSE) agents. Although the proposed CGTP requirements were intended to prevent contamination of HCT/Ps with these agents (e.g., see 66 FR 1508 at 1509, 1510, 1514, and 1515), we believe that these examples of communicable disease make this provision more clear.

A 2002 *Morbidity and Mortality Weekly Report* (MMWR) discusses 26 cases of bacterial infection associated with musculoskeletal allografts and reinforces the importance of following CGTP to prevent the contamination of HCT/Ps with such communicable disease agents. In the MMWR, the Centers for Disease Control and Prevention (CDC) make several significant recommendations on preventing bacterial contamination. Among other things, the CDC states that ''[s]terilization of tissue that does not adversely affect the functioning of tissue when transplanted into patients is the best way to reduce the risk for allograft-associated infections.'' Throughout this final rule, we discuss the CDC's recommendations and note the applicability of specific provisions of the final rule to the prevention of bacterial contamination (Ref. 1).

Core CGTP Requirements (§ 1271.150(b))

Paragraph (b) lists the core CGTP requirements, discussed in section II.D of this document. We have identified the following as core CGTP requirements: § 1271.190(a) and (b) (relating to facilities); § 1271.195(a) (environmental controls); § 1271.200(a) (equipment); § 1271.210(a) and (b) (supplies and reagents); § 1271.215 (recovery); § 1271.220 (processing and process controls); § 1271.250(a) and (b) (labeling controls); § 1271.260(a) through (d) (storage); § 1271.265(a) through (d) (receipt, predistribution shipment, and distribution); and §§ 1271.50, 1271.75, 1271.80, and 1271.85 (donor eligibility determinations, donor screening, and donor testing).

Compliance With Applicable Requirements (§ 1271.150(c)(1))

Proposed § 1271.150(b)(1) states that an establishment that engages in only some operations subject to the regulations in this subpart and subpart C of this part need only comply with those requirements applicable to the operations in which it engages. It further states that when an establishment engages a second establishment to perform any step in manufacturing, the second establishment would be required to comply with the requirements applicable to that manufacturing step. In addition, the first establishment would be responsible for ensuring that the work at the other establishment is performed in compliance with subparts C and D. Proposed paragraph (b) of § 1271.150 has been redesignated as paragraph (c).

The following table summarizes the responsibilities that are assigned in the final rule to each manufacturer when multiple establishments are involved in manufacturing an HCT/P:

TABLE 1A

If you:	You must:
Perform any step in the manufacture of an HCT/P	Follow CGTP (subparts C and D) (§ 1271.150(a)) as it relates to that step.
Perform only some and not all operations of manufacturing, and do not make the HCT/P available for distribution	1. Follow only those requirements applicable to the operations you perform (§ 1271.150(c)(1). 2. When you receive the HCT/P, determine whether the HCT/P meets all pre-established criteria, designed to prevent communicable disease transmission, for acceptance or rejection, and place the HCT/P in quarantine as appropriate (§ 1271.265(a)). 3. When you prepare to ship an HCT/P, ship the HCT/P only in quarantine and after determining criteria designed to prevent communicable disease are met (§ 1271.265(b)). 4. Investigate all HCT/P deviations related to a distributed HCT/P for which you performed a manufacturing step and report any deviation related to core CGTP requirements that occurred in your facility or in a facility that performs a manufacturing step for you under contract, agreement, or other arrangement (§ 1271.350(b)(1) and (b)(2)).
Engage another establishment to perform any step in manufacturing for you under contract, agreement, or other arrangement	1. Enter into and maintain such an arrangement only with a reliable establishment that complies with applicable CGTP requirements. (§ 1271.150(c)(1)). 2. Investigate all HCT/P deviations related to a distributed HCT/P for which you performed a manufacturing step and report any deviation related to core CGTP requirements that occurred in your facility or in a facility that performs a manufacturing step for you under contract, agreement, or other arrangement (§ 1271.350(b)(1) and (b)(2)).

TABLE 1A—Continued

If you:	You must:
Make the HCT/P available for distribution	1. Review manufacturing and tracking records to determine that the HCT/P meets all the release criteria (§§ 1271.150(c)(2) and 1271.265(c)) and maintain records relevant to the release determination (§ 1271.270(a)). 2. Ensure that manufacturing and tracking records demonstrate that the HCT/P has been manufactured and tracked from recovery to the consignee following CGTP (§§ 1271.150(c)(2) and 1271.290). 3. Investigate and report any adverse reaction involving a communicable disease (§ 1271.350(a)). 4. Investigate all HCT/P deviations related to any step in the manufacture of a distributed HCT/P that you performed, and report any HCT/P deviation relating to core CGTP requirements if the deviation occurred in your facility or in a facility that performed a manufacturing step for you under contract, agreement, or other arrangement (§ 1271.350(b)(1) and (b)(2)).

(Comment 28) Several comments objected to the statement in proposed § 1271.150(b)(1) that an establishment that engages another establishment under a contract, agreement, or other arrangement, to perform any step in the manufacturing process, is responsible for ensuring that the work is performed in compliance with the CGTP and donor-eligibility requirements. One comment asserted that the language is too broad and open to interpretation, and could make eye banks responsible for ensuring that entities such as couriers, medical examiner's offices, and laboratories meet regulatory requirements applicable to the subcontracted function. Another comment asked whether an establishment must inspect Federal Express, UPS, or the Postal Service to ensure that they comply with the regulations when shipping corneas.

(Response) We have revised the language of the proposed rule. Under § 1271.150(c)(1), if an establishment (e.g., an eye bank) engages another establishment to perform a manufacturing step, under a contract, agreement, or other arrangement, it must enter into and maintain such an arrangement only with a reliable establishment that complies with applicable CGTP requirements. Under this provision, an establishment should choose its partners with care. This requirement extends to relationships with establishments such as medical examiner offices and laboratories, but it does not apply with respect to carriers, such as Federal Express, UPS, or the Postal Service, who are exempt from the regulations in this part as noted in § 1271.15(c).

(Comment 29) One comment stated that it is unrealistic to require validation of a subcontractor's work on each tissue, and that it is expensive and nearly impossible to find staff with specific expertise to review each type of subcontractor. Another comment stated that eye banks are not qualified to be responsible for ensuring compliance by subcontractors and recommended that compliance by subcontractors be deemed met by a letter of intent from the subcontractor. This comment also asserted that eye banks do not have the expertise to inspect or validate a blood testing laboratory or Bausch & Lomb.

One comment suggested that an initial audit of the contractor should be sufficient. Another comment suggested that each establishment have a system in place designed to ensure that the contractor's work is performed in compliance with the regulatory requirements.

(Response) Section 1271.150(c)(1) is intended to clarify the relationship between you and another establishment that performs one or more steps in manufacture for you (e.g., a procurer engages an outside testing laboratory to perform communicable disease tests for it; a processor engages an outside firm to perform terminal sterilization, such as irradiation, on the final HCT/P). (We have added these examples to the regulation.) You do not have to validate the processes of these outside firms (who are themselves subject to the regulations in part 1271), and we appreciate the fact that you may lack the expertise to do so. However, you are required to enter into and maintain such arrangements only with establishments that comply with applicable CGTP requirements.

We note that there are many ways of performing the due diligence necessary when entering into a manufacturing arrangement with another establishment. The example of an initial audit provided by the comment is one method. Other ways of learning about another establishment before you enter into an arrangement with it might include reviewing test kit package inserts and a testing laboratory's standard operating procedures (SOPs); and reviewing an establishment's compliance history. If you intend to enter into an arrangement with an establishment that does not have a compliance history, review of that establishment's SOPs might assist in ascertaining that entity's compliance status.

Although we recognize the usefulness of an initial audit before entering into an arrangement with another establishment, we note that an initial audit would not satisfy this requirement throughout the term of a continuing relationship. Under § 1271.150(c)(1), you may not ignore information that indicates that a company that performs work for you is not in compliance with applicable CGTP requirements. For example, if you have reason to suspect that an establishment performing work for you is not in compliance with those requirements, you would need to take appropriate action and determine whether the establishment is still in compliance with CGTP. Other regulations in part 1271 may also apply with regard to products manufactured, in part, by an establishment that does not comply with applicable requirements. For example, § 1271.145 provides, ''You must * * * store * * * and distribute HCT/Ps * * * in a way that prevents the introduction, transmission, or spread of communicable diseases.'' You may also have obligations under §§ 1271.160, 1271.265, 1271.320, and 1271.350. If you determine that the establishment is not in compliance with applicable CGTP requirements, you must terminate your contract, agreement, or other arrangement with that establishment. If you determine that an exemption or alternative from this requirement would be consistent with the goals of protecting the public health and/or preventing the introduction, transmission, or spread of communicable diseases, and you either have information that would justify an exemption, or have a proposed alternative that would satisfy the

purpose of this requirement, you may seek an exemption or alternative under § 1271.155.

We intend to issue guidance, which will further elaborate on your responsibilities for ensuring that another establishment that performs one or more steps in manufacture for you is in compliance with part 1271. Our economic impact analysis also indicates that the methods described in this response are not overly costly or burdensome.

(Comment 30) One comment suggested limiting an establishment's responsibility toward contractors to ensuring that the contractor is a registered tissue bank establishment.

(Response) We agree that establishments under contract must register with FDA. However, we note that some individuals who recover cells or tissue under contract, agreement, or other arrangement are excepted from registration under § 1271.15(f); this is one reason that it would not be sufficient to limit an establishment's responsibility to ensuring that a contractor is registered. Moreover, although registration is an important component of the regulation of HCT/P establishments, such a requirement would not go far enough toward safeguarding the public against the communicable disease risks associated with HCT/Ps. Therefore, if you engage another establishment under a contract, agreement, or other arrangement to perform any step in manufacture for you, you must first determine that the establishment complies with applicable CGTP requirements, and you must investigate further if you receive information suggesting that the establishment may no longer be in compliance with those requirements.

Compliance With Applicable Requirements (§ 1271.150(c)(2))

Proposed § 1271.150(b)(2) explained how we would assign ultimate responsibility for an HCT/P. That paragraph states that the establishment that determines that an HCT/P meets release criteria and makes it available for distribution, whether or not it is the actual distributor, is responsible for ensuring that the HCT/P has been manufactured in compliance with the requirement of subparts C and D and any other applicable requirements. In § 1271.150(c)(2), we have added the responsibility for tracking (consistent with § 1271.290).

(Comment 31) Under proposed § 1271.150(b)(2), the establishment that determines that an HCT/P meets release criteria and makes it available for distribution would be responsible for ensuring that the HCT/P has been manufactured in compliance with the requirements in subparts C and D and any other applicable requirements. Several comments agreed with this allocation of responsibility or with the ''cascading'' set of responsibilities discussed in the preamble to the proposed rule, under which

> * * * an establishment would be responsible for ensuring that its own operations comply with applicable requirements, and also would bear the burden of proof that operations performed by other establishments prior to its receipt of the cells or tissue were performed in compliance with applicable requirements (66 FR 1508 at 1512).

One comment asserted that, although the proposed allocation of responsibility was the most reasonable of those considered, it was unclear what sort of documentation would be sufficient to ensure that establishments that handled the HCT/P before receipt were in compliance (in particular, international donor centers), and another comment asserted that proposed § 1271.150(b) would require every company to collect and store documents for all other companies participating in the manufacturing process.

One comment stated that the more prudent approach would be to hold each establishment specifically responsible for the activities that went before. Another proposed that, since more than one establishment may actually make an HCT/P available for distribution, the last establishment that releases the product should be responsible. Another comment recommended that overall responsibility for compliance be assigned only to establishments within the United States.

(Response) We have revised proposed § 1271.150(b)(2) (and renumbered it § 1271.150(c)(2)) to state that if you are the establishment that determines that an HCT/P meets all release criteria and makes the HCT/P available for distribution, whether or not you are the actual distributor, you are responsible for reviewing manufacturing and tracking records to determine that the HCT/P has been manufactured and tracked in compliance with the requirements of this subpart and subpart C of this part and any other applicable requirements. This record review would include, for example, reviewing documentation of donor test results for relevant communicable disease agents to determine that results are negative or nonreactive and that appropriate testing was performed (§§ 1271.80 and 1271.85); matching the distinct identification code on the HCT/P container with the code in the summary of records (§ 1271.290)c); reviewing records pertaining to donor screening for risk factors for and clinical evidence of relevant communicable disease agents (§ 1271.75); reviewing records pertaining to storage temperature (§ 1271.260), processing (§ 1271.220), and other manufacturing steps. The requirement applies to any establishment that makes an HCT/P available for distribution, whether it is foreign or domestic, and whether or not another establishment may later make it again available for distribution. An establishment that makes the HCT/P available for distribution must maintain the records in question.

Section 1271.150(c)(2) ties in closely with § 1271.265, which covers receipt, predistribution shipment, and distribution of an HCT/P. Section 1271.265(c) sets out requirements for making an HCT/P available for distribution, including reviewing records pertaining to the HCT/P, and, on the basis of that record review, verifying and documenting that the release criteria have been met.

(Comment 32) One comment discussed the following scenario. If the first establishment releases the HCT/P to a consignee under its own label, releases it to another distributor, or releases it back to the contracting firm (which may in turn serve as a distributor), then the first establishment is responsible for ensuring that the HCT/P has been manufactured in compliance with CGTP. This comment stated that, if its interpretation of the proposal was correct, then it endorsed the proposal.

(Response) The examples provided by the comment illustrate three different ways in which an establishment might make an HCT/P available for distribution. Under § 1271.150(c)(2), the establishment has the same responsibility in each case: To review manufacturing and tracking records to determine that the HCT/P has been manufactured and tracked in compliance with regulatory requirements.

(Comment 33) One comment asked for further clarification, stating that it is not clear whether the responsibility pertains to the manufacturing facility or just the distributor. If the distributor were an institutional laboratory that receives an HCT/P that was processed at a commercial laboratory, then the requirement would be unduly burdensome, according to the comment.

(Response) In the situation described, the institutional laboratory is not the establishment that makes the HCT/P available for distribution, and would not be ultimately responsible. In fact, an institutional laboratory (e.g., hospital bone bank) that does no further manufacturing of the HCT/P, but only

receives the finished HCT/P from a commercial tissue processor, and ''distributes'' the HCT/P in the same facility, is excepted from these regulations (§ 1271.15(d)). However, if the institutional laboratory performs additional manufacturing steps on the HCT/P, this laboratory is then considered a ''processor'' and is subject to the CGTP requirements.

(Comment 34) One comment asserted that responsibility should be apportioned appropriately among the entities involved. This comment recommended avoiding a situation where screening by various entities would lead to numerous re-contacts of donor families.

(Response) It is not our intention to have various establishments re-contact the donor's family to reconfirm the medical history, for example. The initial establishment that performed the donor medical history interview would document the findings. The establishment that made the HCT/P available for distribution would review the records of the findings to make sure that all release criteria (including donor eligibility) were met, and would retain the documented findings.

(Comment 35) When there are multiple establishments involved in the manufacture of an HCT/P, one comment suggested that we limit the penalties only to the noncompliant establishment.

(Response) Generally, we will not take enforcement action against all parties involved in the manufacturing of HCT/Ps. We will evaluate all available information related to the violative activities and the circumstances concerning the event. If circumstances indicate that multiple parties have not complied with the applicable regulations, we may take enforcement action as appropriate.

Compliance With Applicable Requirements (§ 1271.150(c)(3))

Paragraph (c)(3) of § 1271.150 states that with the exception of §§ 1271.150(c) and 1271.155 of this subpart, the regulations in this subpart are not being implemented for reproductive HCT/Ps described in § 1271.10 and regulated solely under section 361 of the PHS Act and the regulations in this part, or for the establishments that manufacture them.

Compliance With Parts 210, 211, and 820 of this Chapter (§ 1271.150(d))

Proposed 1271.150(c) explains, in part, that for HCT/Ps regulated as biological drugs or devices, the procedures contained in this subpart and in subpart C, and the procedures contained in parts 210, 211, and 820, supplement rather than supersede each other.

(Comment 36) We received one comment on proposed § 1271.150(c). This comment asserted that the last sentence in that paragraph provides no useful guidance and should be deleted. The last sentence in proposed § 1271.150(c) stated

> In the event that it is impossible to comply with all applicable regulations in these parts, the regulations specifically applicable to the biological drug or device in question shall supersede any other requirements. (66 FR 1508 at 1552.)

(Response) In the preamble of the proposed rule, we explained why an HCT/P regulated as a biological drug or device must comply with part 1271 (CGTP) as well as parts 210 and 211 (CGMP) or 820 (QS). CGMP and QS do not contain requirements written explicitly to prevent the spread of communicable disease. CGTP is focused on preventing circumstances that increase the risk of the introduction, transmission, or spread of communicable disease, which makes CGTP regulations less extensive than CGMP and QS regulations. Therefore, CGTP and CGMP or QS are intended to supplement each other. In the event that a regulation in part 1271 is in conflict with a requirement in parts 210, 211, or 820 of this chapter, the regulations more specifically applicable to the product in question will supersede the more general. FDA believes that, in the event of such a conflict, the more specifically applicable regulation would be found in part 1271.

Where Appropriate (§ 1271.150(e))

''Where appropriate'' in proposed § 1271.150(d) would mean that a practice is required unless the establishment can document justification otherwise. A requirement would be considered ''appropriate'' if nonimplementation could reasonably be expected to result in the product's not meeting its specified requirements related to prevention of introduction, transmission, or spread of communicable disease agents and diseases, or in the establishment's inability to carry out any necessary corrective action.

We received no comments on this section.

2. Exemptions and Alternatives(§ 1271.155)

Proposed § 1271.155 sets out the procedures that an establishment must follow to request an exemption from, or an alternative to, a CGTP requirement, as well as the criteria that the Center Director will follow in considering such a request. In the final rule, we have modified § 1271.155(b) to allow requests for exemptions or alternatives to be submitted to the appropriate Center Director (e.g., the Center for Biologics Evaluation and Research (CBER) or the Center for Devices and Radiological Health), rather than only the CBER Director. We have revised § 1271.155(d) for clarity; instead of referring to ''limited circumstances,'' the final regulation states that, if circumstances make it difficult (e.g., there is inadequate time) to submit your request in writing, you may make the request orally.

We have also added § 1271.155(g), which in a public health emergency permits the Director to issue an exemption or alternative to any requirement in part 1271 of title 21 of the Code of Federal Regulations. An exemption or alternative under this section may be necessary to help ensure that certain HCT/Ps will be available in a specified location to respond to an unanticipated immediate need for such HCT/Ps.

(Comment 37) One comment recommended that § 1271.155 should be implemented first, and that the remaining provisions of the rule should be implemented 2 years later.

(Response) We do not agree with this comment. It is not clear why implementation of the exemption provisions should precede implementation of the rest of the final rule. If the requirements are not in effect, then an exemption request is not necessary.

(Comment 38) One comment noted that international establishments that produce peripheral blood stem cells and umbilical cord blood units are subject to their own national and regional regulatory requirements. The comment stated its assumption that these establishments would submit their foreign government's regulations to FDA under § 1271.155.

(Response) The comment's assumption is incorrect. A foreign establishment that distributes HCT/Ps in this country must comply with FDA regulations. It is a foreign establishment's responsibility to determine whether complying with the foreign government's requirements would also satisfy FDA requirements. If a foreign establishment identifies a discrepancy (e.g., an area where FDA regulations are more stringent or in conflict), the establishment may request an exemption or alternative under § 1271.155, and FDA will consider whether the request is justified by the evidence submitted.

(Comment 39) One comment recommended that the rule establish a maximum time period of 30 working

days for an agency decision on a request for an exemption or alternative.

(Response) Although we agree that timely decisions are important, we disagree that this regulation should contain a specific timeframe. Depending on the nature of the request, more or less time may be needed to give the request adequate consideration. We note that other FDA regulations dealing with exemptions do not specify a deadline for a reply (see, e.g., § 640.120 (21 CFR 640.120) and 21 CFR 803.19). The time for our review of requests under § 640.120 for variances related to the blood regulations has varied from two weeks to four months, depending on the complexity and urgency of the request. We intend to respond to variance requests under § 1271.155 within similar timeframes, with our time to respond tied to the complexity and urgency of the request.

(Comment 40) One comment asserted that the criteria in proposed § 1271.155(c) for granting an exemption or alternative are too narrow, in that they do not afford an establishment an exemption or alternative to a particular requirement not relevant to the tissue in question. The comment suggested adding the phrase: ''and that such goals are not impaired by an exemption or alternative.''

(Response) We disagree with this comment. The suggested language is unnecessary and would narrow the criteria for granting an exemption or alternative. We note that if a requirement is not relevant to a particular establishment's operations, it is not necessary to request an exemption (§ 1271.150(c)(1)).

We have, however, modified the criteria for granting an exemption or alternative in § 1271.155(c) to permit the Center Director greater flexibility in responding to critical medical needs. That paragraph now reads, in part

> The Director may grant an exemption or alternative if he or she finds that such action is consistent with the goals of protecting the public health and/or preventing the introduction, transmission, or spread of communicable disease.

(Comment 41) One comment noted that proposed § 1271.155(d) and (e) are internally inconsistent, because paragraph (d) would allow for an oral request and reply, but paragraph (e) states that an establishment must not begin operating under the terms of a requested exemption or alternative until it had been granted in writing. The comment asked us to clarify that orally granted exemptions and alternatives would have immediate effect, and that an establishment would not be required to wait for a written statement from the agency.

(Response) We agree with this comment and have deleted the words ''in writing'' from § 1271.155(e).

(Comment 42) Another comment stated that FDA should evaluate how a small entity may qualify for reasonable exemptions and alternatives.

(Response) We have written § 1271.155(b) to apply to both large and small entities. Supporting documentation that either justifies a requested exemption, or describes a proposed alternative, must accompany a request. To assist all establishments, large and small, in pursuing appropriate exemptions and alternatives, we intend to make available to the public on the CBER Web site information concerning exemptions and alternatives that have been granted, while following statutory requirements prohibiting public disclosure of confidential information.

3. Quality Program (§ 1271.160)

Proposed § 1271.160 would require an establishment that performs any step in the manufacture of an HCT/P to establish and maintain a quality program that is appropriate for the specific HCT/Ps manufactured and the manufacturing steps performed, and that meets the requirements of subpart D of part 1271.

Section 1271.160 of this final regulation requires instead that the quality program address all core CGTP requirements. We have also removed two items from the list in § 1271.160(b) of a quality program's functions: Proposed paragraph (b)(5) (on monitoring systems) and proposed paragraph (b)(6) (on record maintenance systems).

(Comment 43) One comment strongly supported the requirement for a quality program. Another comment appreciated the differentiation between the quality program and the quality system requirement for devices and blood products. This comment stated that giving tissue banks flexibility in how defined functions are accomplished, and not requiring the employment of staff free of other responsibilities, recognizes the undue burden that it would create. In contrast, two other comments asserted that eye banks would have to hire separate quality control employees, which would be time consuming and expensive.

(Response) We appreciate the comments supporting the requirement. We note that the regulation does not require an establishment to hire a separate quality control employee; moreover, we have removed the requirement for the designation of an individual with authority over the program (proposed § 1271.160(c)).

(Comment 44) Two comments supported the idea that a quality program should be commensurate with the manufacturing steps performed and the types of tissues involved. These comments requested that FDA distinguish between ''quality programs'' and other quality requirements, to ensure that establishments are not held to unsuitable quality requirements.

(Response) The quality program required under § 1271.160 is a system that each establishment sets up to ensure its compliance with core CGTP requirements. These regulations do not contain generalized quality requirements.

(Comment 45) We received three comments on proposed § 1271.160(b)(2), which would require procedures for sharing with other establishments that are known to have recovered cells or tissue from the same donor any information pertaining to the possible contamination of the HCT/P or the potential transmission of communicable disease by the HCT/P. One comment asserted that it would not be appropriate to share information about an autologous donor's baseline viral status with another establishment. This comment also expressed concern that the required procedure would be inconsistent with the requirement in proposed § 1271.270 pertaining to donor confidentiality. The other two comments suggested narrowing the provision so that establishments would not be required to disclose proprietary information to competitors.

(Response) We decline to modify the requirement as requested. The purpose of this requirement is to ensure that, if an establishment learns that a donor is ineligible or that an HCT/P is contaminated, the establishment has a procedure in place for informing consignees and other establishments that are known to have recovered cells or tissues from the same donor. Recognizing that other establishments may have received HCT/Ps from the same donor, even if they did not recover them, we have added to this list, ''other establishments that are known to have performed manufacturing steps with respect to the same HCT/P.''

There is no requirement that an establishment disclose customer lists, manufacturing processes, or other proprietary information to competitors. Moreover, these procedures can be designed so that patient confidentiality is not compromised.

With respect to the comment on sharing information about an autologous donor, we are unable to envision a

situation where this requirement would necessitate such a disclosure. Since HCT/Ps for other recipients would not be recovered from the autologous donor, there would be no need to share information regarding the donor's baseline viral status.

(Comment 46) Proposed § 1271.160(b)(7) would require establishments to investigate and document all product deviations in manufacturing. (These are now referred to as ''HCT/P deviations.'') One comment asserted that product deviation review and analyses should be treated in the same manner as internal audits (i.e., not available for review on inspection). Two comments asserted that the periodic audit of product deviations and collation of complaint files are tools of quality management and that FDA should guarantee the confidentiality of these quality management activities.

(Response) We have renumbered proposed paragraph (b)(7) as (b)(6) and removed the requirement for a periodic review and analysis of HCT/P deviations. Under the final regulation, you are required to investigate and document HCT/P deviations and trends of HCT/P deviations relating to core CGTP requirements and to make reports if required to do so under § 1271.350(b) or other applicable regulations.

(Comment 47) One comment requested that we limit the requirement for reporting product deviations to those identified post-release.

(Response) The reporting requirement in § 1271.350(b)(1) applies only to distributed HCT/Ps, regardless of the time at which the deviation is identified.

(Comment 48) Two comments asked us to clarify that § 1271.160(b)(7) includes only product deviations in manufacturing that would increase the risk of disease transmission.

(Response) The term ''HCT/P deviation'' is defined in § 1271.3(dd) of this final rule to include events that may increase the risk of communicable disease transmission, because they: (1) Represent a deviation from applicable regulations in this part or from applicable standards or established specifications relating to the prevention of communicable disease transmission or HCT/P contamination, or (2) constitute an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease or may lead to HCT/P contamination.

(Comment 49) Under proposed § 1271.160(c), one or more designated persons would have authority over the quality program, and these persons would report to management at least once a year on the performance of the quality program, unless more frequent reports are necessary. If these persons also perform other tasks in the establishment, they must not have final oversight over their own work.

Two comments on this provision asserted that the requirement for independent oversight is too stringent. One comment stated that, in small laboratories with only a single technician, it may not be possible for an independent person to have oversight. The other comment recommended that the oversight requirement be dropped as costly and impracticable.

(Response) We have removed this requirement from the final rule.

Audits

(Comment 50) One comment requested more flexible language to replace the requirement for a comprehensive quality audit no less than once in 12 months. Another comment asserted that the requirement for an annual comprehensive audit is more stringent than the requirements applicable to blood component processing.

(Response) In response to these comments, we have revised proposed § 1271.160(d). Section 1271.160(c) now requires only that a quality audit of core CGTP activities be performed periodically for management review. The new language provides establishments with a greater degree of flexibility in determining how and when to audit their quality programs. We also may issue future guidance making recommendations on what we would consider to be a periodic audit.

(Comment 51) Two comments asserted that internal audit findings should not be available to FDA representatives.

(Response) With respect to quality audits, while some firms choose to provide quality audits to FDA, FDA's current practice is generally not to review or copy the actual quality audit reports during routine inspections and investigations except in certain limited circumstances (FDA Compliance Policy Guide 130.300). However, the firm should have a mechanism to demonstrate to the FDA representative that quality audits are being performed and that corrective actions are being implemented when problems are identified.

Computers

Proposed § 1271.160(e) would require establishments to validate computer software used as part of manufacturing or tracking or for maintaining data relating to those activities.

(Comment 52) One comment asserted that it is reasonable to require that computer systems used in manufacturing and data maintenance be tested to confirm that they perform as intended, and that the testing and results be documented. This comment asked us to confirm that we are distinguishing between this limited requirement and the term ''validation'' as it has been applied to computer systems identified as medical devices.

(Response) We agree with this comment. Therefore, we revised the requirement in § 1271.160(d) to permit verification or validation of the computer software for its intended use.

(Comment 53) Several comments opposed the proposed requirement on computer software validation. One comment asserted that software validation can be a financial burden and stated that the requirement should be implemented to the extent validation will minimize the risk of disease transmission during the manufacturing process. The comment further noted that there was no exemption in this provision for general-purpose software (e.g., spreadsheet, database, and word processing software) intended for broad general use, which are currently exempt from most of the general controls under the act. Two comments suggested limiting the scope of the requirement to the most necessary areas, to encourage the use of software programs in lieu of manual recordkeeping. Another comment asked that we amend the provision to reflect that software must be validated only if it is relied upon as the sole data source for the decisionmaking processes of the quality system.

(Response) We do not intend that the requirements for computer validation be unduly burdensome. As a result of these comments, we are modifying the requirements in § 1271.160(d). This section now applies only to software that you rely upon to comply with core CGTP requirements. You must validate the performance of software for its intended use only if the software is custom software or commercially available software that has been customized or programmed (including software programmed to perform a user-defined calculation or table) to perform a function related to core CGTP requirements. If you rely on commercially distributed, noncustom, software to perform a function related to core CGTP requirements, then you are only required to verify the performance of that software for its intended use. With these changes, we have limited the scope of this provision so that it applies to computer software that directly

affects communicable disease transmission risks. If such software is inappropriately designed, implemented, or used, the software may increase the risk of communicable disease transmission, perhaps by authorizing the release of HCT/Ps from an infectious donor, or by recording screening test results inaccurately. However, we recognize that commercially distributed general use software has undergone more rigorous testing before it is distributed. When such general use software is used without modification to comply with core GTP requirements, it is adequate for the establishment only to verify the performance of the software for its intended use, rather than undertaking more onerous validation.

For example, an eye bank that uses commercially distributed software (e.g., spreadsheet, database, word processing) to comply with a core CGTP requirement such as control of storage areas (§ 1271.260(a)), but not for making decisions or determinations, must verify that this general purpose software can be used reliably in such a way, but would not have to validate the software. Verification in a situation such as this is not intended to be onerous. However, if the eye bank decided to modify and use commercially available computer software for determining donor eligibility, the modifications would increase the risk of problems and the eye bank would then be required to validate the software for this intended use.

(Comment 54) One comment noted that eye banks do not use computers as decisionmaking instruments, but only for information storage and retrieval, word processing, and form printing. This comment asserted that appropriate validation in this instance should entail: (1) Routine backup of computer system, (2) physical check of computer printout against paper chart, and (3) signoff by final supervisor before tissue release.

(Response) The examples provided are not core CGTP requirements and so the requirements of § 1271.160(d) would not apply.

4. Organization and Personnel (§ 1271.170)

Proposed § 1271.170 would require establishments to maintain an adequate organizational structure and sufficient personnel with the necessary education, experience, training and retraining to ensure competent performance of their assigned functions. Personnel records documenting these requirements would be required.

(Comment 55) Two comments supported § 1271.170 as proposed. One comment agreed that tissue bank personnel should be educated concerning the possible consequences of improperly performing their duties, and noted that unacceptable tissue practices could have monumental implications in disease transmission. This comment further asserted that recordkeeping on personnel training is appropriate.

(Response) We appreciate the supportive comments. However, we have removed both of these proposed requirements from § 1271.170. Section 1271.170 also does not require an establishment to maintain an adequate organization structure.

(Comment 56) One comment asserted that FDA should set guidelines for the credentials of tissue bank directors.

(Response) We have not included in the regulations requirements for specific credentials. Instead, we require that personnel have the necessary education, experience, and training to ensure competent performance of their assigned functions. Professional organizations, accrediting bodies, and States may decide to develop guidelines for certain personnel credentials.

(Comment 57) One comment from a professional organization suggested replacing the phrase ''education and experience'' in proposed § 1271.170(b) with ''training and documentation of competency.''

(Response) We agree with the comment that ''training'' should be added to the requirements in § 1271.170(b), and we have made this change; however, we disagree with the proposal to remove ''education and experience.'' As revised, § 1271.170(b) requires you to have personnel with the necessary education, experience, and training to ensure competent performance of their assigned functions.

(Comment 58) One comment on proposed § 1271.170(c) asserted that it is unclear what criteria a company should use to determine the qualifications of laboratory personnel.

(Response) There are a variety of ways to comply with the requirement in § 1271.170(c) that an establishment train all personnel to perform their assigned responsibilities adequately. Each establishment should establish its own criteria. Some examples of criteria an establishment might use to determine the qualifications of laboratory personnel include: Achievement of a minimum score on a written test, direct observation and evaluation by a supervisor, successful completion of continuing education courses (e.g., passing an examination), accreditation or proficiency testing by an outside organization.

5. Procedures (§ 1271.180)

Proposed § 1271.180 would require establishments to establish and maintain procedures for all significant steps that it performs in the manufacture of HCT/Ps.

We have reorganized § 1271.180 by dividing it into paragraphs for greater clarity and ease of reading. In addition, § 1271.180 now requires you to establish and maintain procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps and further requires that these procedures be designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases through the use of HCT/Ps.

We note that, depending on the activities that you perform, your procedures may need to cover such issues as the length of time a cadaver may be stored, or the conditions of storage (e.g., temperature). Moreover, to prevent the recovery of contaminated cells or tissues, you need to establish and maintain procedures to prevent the recovery of cells or tissue from a septic donor or from an area of the body where there is a localized infection. The MMWR report cited in section III.C.1 of this document (Ref. 1) discussed a case in which tissue probably became hematogenously seeded by bowel flora before harvesting. The report noted that factors that may contribute to such contamination include the time interval between death and tissue retrieval, delays in refrigeration, and mode of death (e.g., trauma). The procedures of an establishment that recovers cells and tissue should appropriately address these possible causes of HCT/P contamination to comply with § 1271.180(a).

(Comment 59) One comment supported the section as proposed. Another comment asked for examples of what does or does not constitute a ''significant step'' and asked how it differs from ''any step'' in the quality program requirements.

(Response) A ''significant step'' is a step in manufacturing listed in the definition of ''manufacture'' in current § 1271.3(e), i.e., all steps in the recovery, processing, storage, labeling, packaging, or distribution, and the screening and testing of the donor, and is not considered different from ''any step in the manufacture of human cellular and tissue-based products.'' Therefore, we have removed the term ''significant'' from § 1271.180(a).

(Comment 60) Proposed § 1271.180 would require establishments to review

and, if necessary, revise all procedures at least once in a 12-month period. One comment objected to the specificity of this requirement, citing the more flexible requirements in the CGMP and QS regulations.

(Response) We agree with this comment and note that the comparable requirements in the CGMP and QS regulations (§§ 211.100 and 820.40) do not require an annual review of procedures. For this reason, we are deleting the proposed requirement in § 1271.180 that all procedures be reviewed on an annual basis. However, we note that the periodic quality audit required under § 1271.160(c) should include a review of an establishment's SOPs.

(Comment 61) Several comments objected to the proposed requirement that deviations from procedures be authorized in advance, because deviations are not foreseeable and cannot be authorized before they occur. One comment suggested requiring a justification for the deviation to be recorded at the time of the occurrence, and requiring approval of the deviation by a responsible person before release of the tissue.

(Response) We agree with these comments and have modified the requirement in accordance with the suggestion; the requirement, which is now located in § 1271.265, requires an establishment to record and justify any departure from a procedure at the time of its occurrence, rather than before. (We replaced the word ''deviation'' with the word ''departure'' to avoid confusion with the defined term ''HCT/P deviation.) The provision further states that you must not make available for distribution any HCT/P manufactured under a departure from a procedure designed to protect against risks of communicable disease transmission, unless a responsible person has determined that the departure does not increase the risk of communicable disease transmission through the use of the HCT/P. For example, if the technician at the recovery site uses a different brand of sterile gauze because the brand stated in the standard operating procedures is not available, the establishment may make the HCT/P available for distribution provided that the departure was recorded and justified at the time, and the responsible person determines that the substitution did not increase the risks of communicable disease transmission.

(Comment 62) Proposed § 1271.180 would require obsolete procedures to be archived for at least 10 years. One comment suggested that a longer retention period of 10 years after transplantation would be more appropriate and consistent with record retention requirements in § 1271.270.

(Response) We have removed this requirement from the final regulation. However, although we do not require you to retain obsolete procedures, under § 1271.270(d) you are required to retain records for 10 years unless otherwise stated.

6. Facilities (§ 1271.190)

Proposed § 1271.190 would require that any facility used in the manufacture of products be of suitable size, construction, and location to facilitate cleaning, relevant maintenance, and proper operations; be maintained in a good state of repair; and have adequate lighting, ventilation, plumbing, drainage, and washing and toilet facilities. Proposed § 1271.190 also contained requirements relating to the division of a facility into operational areas, and relating to facility cleaning and sanitation.

Section 1271.190 has been reorganized.

(Comment 63) Three comments objected that proposed § 1271.190 is too broad and asserted that it should be limited to requirements for preventing the transmission of disease. Two comments suggested new language.

(Response) In response to these comments, we have revised the language of § 1271.190, reflecting the suggested language. The first sentence of § 1271.190(a) now states that any facility used in the manufacture of HCT/Ps ''must be of suitable size, construction, and location to prevent contamination of HCT/Ps with communicable disease agents and to ensure orderly handling of HCT/Ps without mixups.''

(Comment 64) One comment on proposed § 1271.190(a) questioned the interpretation of ''suitable size, construction, and location.'' Another comment asked us to clarify the meaning of ''location.''

(Response) As discussed in the previous comment, we have changed the wording of § 1271.190(a) to make it clear that the suitability of a facility's size, construction, and location relates to preventing the contamination of HCT/Ps with communicable disease agents and ensuring orderly handling of HCT/Ps. We do not believe any other change is necessary. We decline to dictate specific requirements for an HCT/P establishment's size, construction, and location; it is more appropriate for establishments to make these determinations for themselves, based on the objectives set out in this regulation.

By location, the regulation refers to the facility's site. Some examples of unsuitable locations for an HCT/P establishment, because of the risk of transmission of communicable disease, might include a site on a loading dock or in the same building as a slaughterhouse.

(Comment 65) One comment asserted that, if an establishment is a tenant in a building, then bringing a problem to the attention of the building management, with the understanding that a response would occur in a reasonable time period, should be an acceptable way of complying with this section.

(Response) An establishment that is a tenant should ensure that, under its rental agreement, the landlord will undertake the activities required in this section on a routine basis and within a reasonable amount of time. In this situation, a responsible establishment would communicate regularly with the landlord to bring problems to the landlord's attention in a timely manner. However, if a facility's conditions are such that the establishment is unable to manufacture HCT/Ps in an acceptable manner, then manufacturing activities should stop immediately; in this situation, where immediate repairs are required, simply notifying the landlord is not sufficient.

(Comment 66) One comment requested a modification to proposed § 1271.190(a) to delete the requirement for toilet facilities.

(Response) We decline to delete the requirement for toilet facilities. However, we have modified the requirement so that it now refers to ''access to sinks and toilets.'' As modified, the regulation requires toilets to be accessible, but not necessarily within the establishment. We have further revised the last sentence of paragraph (a) to state that you must provide lighting, ventilation, plumbing, drainage, and access to sinks and toilets to prevent the introduction, transmission, or spread of communicable disease.

(Comment 67) One comment on proposed § 1271.190(c) asserted that developing and maintaining procedures for routine cleaning and maintenance, such as trash removal, cleaning toilets, and sweeping floors, would be a waste of time and resources.

(Response) We disagree. Maintaining a clean facility is fundamental to an establishment's ability to prevent the contamination of HCT/Ps. Without procedures in place, this important responsibility may be left to chance. An establishment's procedures might state, for example, how often a particular floor

is to be mopped and which disinfectant must be used. Such procedures are basic elements of communicable disease prevention and are not trivial matters.

We recognize, however, that not all cleaning and sanitation that you may perform will relate to these requirements (e.g., vacuuming the lobby); thus, we have modified paragraph (d)(1) to limit its scope to procedures for facility cleaning and sanitation for the purpose of preventing transmission of communicable disease. We have made a similar change to paragraph (b)(1), which now requires you to maintain facilities in a clean, sanitary, and orderly manner, to prevent the transmission of communicable disease.

The requirements for facility cleaning in proposed paragraphs (c)(1) and (c)(2) are now in paragraph (b); the requirement for procedures in proposed § 1271.190(c)(3) is contained in § 1271.190(d)(1); and the requirement for record retention in proposed § 1271.190(c)(4) is contained in § 1271.190(d)(2).

(Comment 68) Another comment asked for clarification of the phrase ''significant cleaning and sanitation activities'' in proposed § 1271.190(c)(4). This comment opposed a requirement to keep mopping records for 10 years, but supported keeping records of changing the air handling filters.

(Response) For clarity, we have removed the word ''significant'' from § 1271.190(c)(4), now renumbered as paragraph (d)(2). This paragraph now requires you to document and maintain records of ''all cleaning and sanitation activities performed to prevent contamination of HCT/Ps.'' Generally, cleaning and sanitation activities performed in the manufacturing area would be performed to prevent contamination of HCT/Ps, while these activities performed elsewhere in the establishment (e.g., business offices, lobby) would not be performed for that purpose. Thus, all sanitation activities in certain areas would need to be documented. Although it is not necessary to maintain actual mopping records, you do need to document that cleaning in accordance with procedures took place (e.g., by having the person performing this task initial a log).

We also agree with the comment regarding record retention and we have revised the requirement for retaining records of facility cleaning and sanitation activities from 10 years to 3 years, which allows the records to be available for an inspection cycle.

7. Environmental Control and Monitoring (§ 1271.195)

Proposed § 1271.195 would require establishments to establish and maintain procedures to adequately control and monitor environmental conditions and to provide proper conditions for operations. It would also require inspections and recordkeeping.

We have reorganized § 1271.195. The requirement for environmental monitoring in proposed paragraph (a) is now contained in paragraph (c). Moreover, paragraph (a) no longer requires the establishment and maintenance of procedures for the control and monitoring of environmental conditions. That paragraph now states, in part, that ''you must adequately control environmental conditions.''

(Comment 69) Three comments discussed the applicability of this section to eye banking. One comment asserted that because corneas remain in closed, sealed vials once final placement in media occurs, the requirement for control and monitoring of ventilation and air filtration systems would not apply. Two other comments cited the use of laminar flow hoods in work on eye tissue and argued that the installation of a major environmental control system would be cost prohibitive and unnecessary.

(Response) Rather than require environmental control and monitoring by all establishments in all situations, we have adopted a flexible approach that allows each establishment to assess its particular needs. Thus, § 1271.195(a) requires environmental control and monitoring ''where environmental conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable disease agents.'' In those situations, you must adequately control environmental conditions and provide proper conditions for operations. The regulation lists control activities or systems that must be employed, where appropriate. (''Where appropriate'' is explained in § 1271.150(e).) It may not be necessary to institute a facility-wide control system in situations where work on HCT/Ps is performed in a controlled environment (e.g., use of a laminar hood that is subject to control).

(Comment 70) Proposed § 1271.195(a)(3) would require cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations, where appropriate. Two comments asserted that, where other control systems to prevent contamination are in place, cleaning and disinfection of rooms and equipment are not necessary.

(Response) The regulation allows establishments to develop environmental control systems that are appropriate to their activities. If control systems are in place to prevent contamination, then an establishment should institute measures to ensure that these controls are performing as intended. It appears unlikely, however, that cleaning and disinfection would not be a necessary component of controls.

(Comment 71) Proposed § 1271.195(a)(5) would require environmental monitoring for organisms, where appropriate. One comment asserted that there is no expert consensus on which organisms to monitor and that the regulation should be more specific.

(Response) We agree that there is no expert consensus on a single list of organisms for which all facilities should monitor; however, we disagree that it is necessary for us to provide a list in this regulation. Conditions may differ from facility to facility (and even from room to room within a facility), with common microorganisms found in one area but not another. Each establishment should determine the microorganisms that may exist in its facilities and design its monitoring program accordingly.

FDA has issued a draft guidance document entitled ''Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing, Current Good Manufacturing Practice,'' dated August 2003, (*http://www.fda.gov/cber/gdlns/steraseptic.htm*) that may provide useful information to an HCT/P establishment that is developing procedures on environmental control and monitoring. Information on environmental monitoring may also be found in the U.S. Pharmacopoeia.

The requirement for monitoring for microorganisms in proposed § 1271.195(a)(5) has been moved to § 1271.195(c).

8. Equipment (§ 1271.200)

Proposed § 1271.200 would require that equipment used in the manufacture of HCT/Ps be appropriately designed for its use, and be suitably located and installed to facilitate operations, including cleaning and maintenance. It also contained requirements for procedures and schedules, calibration of equipment, inspections, and records.

(Comment 72) One comment asserted that the proposed requirement is overly broad and that the regulation should allow establishments to write and

maintain procedures for use of equipment, cleaning, and calibration that prevent circumstances that increase the risk of introduction, transmission, or spread of communicable disease. Another comment asked whether the requirements in § 1271.200 should be limited to concerns of communicable disease transmission.

(Response) We agree with the comments that § 1271.200 should be limited to concerns of communicable disease transmission. Therefore, the first sentence of § 1271.200(a) now reads

> To prevent the introduction, transmission, or spread of communicable diseases, equipment used in the manufacture of HCT/Ps must be of appropriate design for its use and must be suitably located and installed to facilitate operations, including cleaning and maintenance.

Under § 1271.200(b), an establishment must establish and maintain procedures for cleaning, sanitizing, and maintaining equipment to prevent malfunctions, contamination or cross-contamination, accidental exposure of HCT/Ps to communicable disease agents, and other events that could reasonably be expected to result in the introduction, transmission, or spread of communicable diseases.

(Comment 73) Several comments asked that vendor validation and maintenance records be acceptable for compliance with § 1271.200.

(Response) You may use vendor validation and maintenance records to demonstrate compliance with § 1271.200; however, you are still responsible for having a system in place designed to ensure that the services provided by the contractor are adequate and in compliance with applicable requirements. Section 1271.150 addresses the question of work performed by other establishments or contractors.

(Comment 74) Proposed § 1271.200(a) would require, in part, that any automated, mechanical, electronic, computer, or other equipment used for inspection, measuring, and testing be capable of producing valid results. One comment asked us to clarify the meaning of ''valid results'' in proposed § 1271.200(a). The comment stated that valid results may be obtained through appropriate validation and/or calibration of equipment.

(Response) We agree that ''capable of producing valid results'' does not mean validation of equipment. The requirement is for the equipment to work properly, thereby providing ''valid results.'' This may be accomplished by calibrating, inspecting, and maintaining equipment. (See e.g., ''Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation,'' 61 FR 52602, October 7, 1996.)

(Comment 75) Proposed § 1271.200(c) would require calibration of all automated, mechanical, electronic, computer, or other equipment used for inspection, measuring, and testing. One comment objected to the requirement for calibration of computers because computers do not make measurements, and asserted that validation should be sufficient. Another comment stated that the calibration of slit lamps is not practical.

(Response) We have revised paragraph (c) in response to these comments. First, we have removed computers from the listed types of equipment in this paragraph and in paragraph (a). Second, we have added ''where appropriate'' to the first sentence of the paragraph. We have made these changes because we recognize that there are certain pieces of equipment that cannot be calibrated (e.g., computers, slit lamps). We have also removed the second and third sentences of proposed paragraph (c), which related to direction for calibration; accuracy and precision limits; and corrective actions.

(Comment 76) Approximately eight comments objected to the requirement in proposed § 1271.200(e) that records of recent maintenance, cleaning, sanitizing, calibration, and other activities be kept ''at each piece of equipment.'' One comment recommended that facilities be allowed the flexibility to maintain the records in a location that is easily accessible to the equipment but not directly at the equipment site. Another comment agreed that these records must be maintained but noted that it is important to keep the amount of paper to a minimum in a clean room environment and suggested that the documents need only be readily retrievable. One comment noted that records cannot physically be kept on small instruments such as pipettes and suggested the use of a central repository.

(Response) We agree with these comments and have revised the regulation. Section 1271.200(e) now states, in part, that you must display records of recent maintenance, cleaning, sanitizing, calibration, and other activities on or near each piece of equipment, or make the records readily available to the individuals responsible for performing these activities and to the personnel using the equipment. This new language, which is based on § 820.72, provides establishments with more flexibility than the proposed provision would have given.

(Comment 77) One comment asserted that the records requirement in proposed § 1271.200(e) should be limited to major equipment and should not include simple instruments that are regularly washed and disinfected or disposable equipment that has a validated procedure for cleaning and disinfecting.

(Response) We disagree with the suggestion to exempt simple instruments from the requirements of this rule. Records for cleaning and maintenance of instruments, tools, and other equipment used or reused in the manufacturing of HCT/Ps must be kept to document that the items were adequately cleaned and maintained to prevent their contamination or cross-contamination by communicable disease agents. Single-use instruments, tools, or other equipment would not be subject to the requirement if they are used only one time and are disposed of after use.

9. Supplies and Reagents (§ 1271.210)

Proposed § 1271.210 would require the establishment to establish and maintain procedures for receiving supplies and reagents used in the manufacture of HCT/Ps. These items would be verified to meet specifications designed to prevent circumstances that increase the risk of introduction, transmission, or spread of communicable disease through HCT/P contamination. Supplies and reagents are materials that might be used during manufacture, but do not include any material that might become a component of an HCT/P (66 FR 1508 at 1515).

We have reorganized § 1271.210. The requirement for validation or verification of the production of in-house reagents is now in paragraph (c) and refers to processes instead of procedures; records requirements are now in paragraph (d).

(Comment 78) One comment supported the regulation as proposed, noting however that compliance would be costly.

(Response) We address concerns about compliance costs separately, in section V of this document.

(Comment 79) One comment on proposed § 1271.210(a) questioned whether the receipt requirements pertained to supplies used solely in the recovery of human tissues.

(Response) Section 1271.210 applies to all steps in the manufacture of HCT/Ps, including recovery. Use of a contaminated or otherwise defective supply or reagent in the manufacture of an HCT/P could lead to such problems as the introduction of a disease agent or

the failure to properly preserve the HCT/P. It is important for establishments to establish and maintain procedures for receiving supplies and reagents, including verification, at each step of manufacture, beginning with recovery. We note that § 1271.210(a) no longer contains a requirement for procedures. However, § 1271.210(a) and (b) are core CGTP requirements listed in § 1271.150(b); therefore, the requirement for establishing procedures under § 1271.180 applies to these two paragraphs.

(Comment 80) One comment asked whether vendor verification is required for all supplies or only for those that come in contact with the donor or the recovered tissue.

(Response) Verification by you or the supply vendor is required for all supplies and reagents that may be used in the course of manufacture, not simply those that may come in contact with a donor or an HCT/P. For example, a reagent used in donor testing must be verified, even if it does not come into contact with the donor or the donated tissue.

(Comment 81) One comment asserted that the requirement is overly broad and requested that we allow establishments to write and maintain procedures for use of supplies and reagents that prevent circumstances that increase the risk of introduction, transmission, or spread of communicable disease.

(Response) We have narrowed § 1271.210 to apply more specifically to preventing the introduction, transmission, or spread of communicable diseases.

(Comment 82) Proposed § 1271.210(c) contains records requirements, and paragraph (c)(3) would require records of the use of each supply or reagent, including the identification of each HCT/P manufactured with the supply or reagent. One comment noted that, for many HCT/Ps, lots are small, and a requirement for separate records would present an enormous burden. Another comment questioned the utility of listing each product processed by each pipette or bottle of medium. A third comment asserted that, although the processing records for each hematopoietic stem/progenitor cell preparation should identify supplies and reagents used for processing, it would be prohibitively time-consuming to maintain separate records of each transplant prepared with each reagent.

(Response) You should establish a system under which particular lots of supplies and reagents can be linked to individual HCT/Ps. This does not require an individual record for each HCT/P prepared with each reagent, as the comment suggested. Therefore, we have added ''lot'' to renumbered paragraph (d)(3) to make clear the lesser burden. We have also added ''quantity'' so that the establishment may find all supplies and reagents received in the event of a recall by the manufacturer. Maintaining the records required in paragraph (d)(3) will enable you to do a cross-check to determine which lots of supplies and reagents were used at a particular time and which HCT/Ps were processed during that same time period (e.g., if there is a recall of a particular lot of reagent or supplies).

10. Recovery (§ 1271.215)

This final rule includes a new section specific to the recovery of cells and tissues, § 1271.215. This section states that, if you are an establishment that recovers HCT/Ps, you must recover each HCT/P in a way that does not cause contamination or cross-contamination during recovery, or otherwise increase the risk of the introduction, transmission, or spread of communicable disease through the use of the HCT/P. This requirement was implicit in the proposed rule (e.g., § 1271.180); however, in reorganizing the rule we have determined that it is necessary to make this requirement explicit. Section 1271.215 is listed as a core CGTP requirement in § 1271.150(b). As discussed in section III.C.5 of this document, you must establish and maintain procedures for cell and tissue recovery.

11. Processing and Process Controls (§ 1271.220)

Proposed § 1271.220 would require an establishment engaged in processing to develop, conduct, control, and monitor its manufacturing processes to ensure that each HCT/P conforms to specifications, is not contaminated, and is manufactured so as to prevent transmission of communicable disease by the HCT/P. Proposed § 1271.220 also contains requirements with respect to processing materials, pooling, and in-process monitoring.

We have moved the provision on dura mater from proposed § 1271.230(c) to § 1271.220(d); we address comments on the proposed provision with other comments on proposed § 1271.230.

(Comment 83) One comment requested an exemption for eye banks from this section, because corneas are not processed in accordance with FDA's definition. Another comment asserted that the section is inapplicable to eye banks.

(Response) We disagree. Eye banks that perform even minimal processing must control their processes. At Comment 21, we explain the applicability of the term ''processing'' to eye banking.

(Comment 84) Proposed § 1271.220(a) would require, in part, that each establishment develop, conduct, control, and monitor its manufacturing processes to ensure that each HCT/P conforms to specifications. One comment required that we define ''specifications.'' Another comment noted that there are no specifications set for corneas, but that criteria are determined by local medical directors in conjunction with professional standards.

(Response) Requirements with respect to in-process control and testing are now contained in § 1271.220(c). We have also removed references to specifications from § 1271.220(a). That paragraph now requires that, if you are an establishment that processes HCT/Ps, you must process each HCT/P in a way that does not cause contamination or cross-contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P.

We recognize, however, that the term ''specifications'' appears elsewhere in this regulation (e.g., § 1271.3(dd), definition of ''HCT/P deviation''). We noted in the preamble to the proposed rule that, by ''specifications,'' we meant those criteria established by a manufacturer for an HCT/P that must be met at defined stages in the manufacturing process and before the product is made available for distribution (66 FR 1508 at 1516). Ordinarily, an establishment will set specifications for various operations within its facility, not just processing. Because we believe the term is generally well understood, we do not consider it necessary to define the term in this rule.

As noted in our response to Comment 19, we understand that an eye bank might not set specifications for corneas. However, we expect that an establishment will generally set out acceptability criteria for its HCT/Ps in its standard operating procedures.

(Comment 85) One comment requested clarification of the requirement for monitoring and control of validated processes. This comment asked if the quality review is sufficient to ensure that specific processes continue to be met.

(Response) We have removed from § 1271.220(a) the specific requirement for monitoring and control of processes. However, we believe that, to ensure that you are processing HCT/Ps in a way that does not cause contamination or cross-

contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P, a firm should establish appropriate, objective mechanisms to control and monitor each validated process. This may include a variety of activities, e.g., statistical process-control methods, review of product acceptance criteria and results, as well as a meaningful quality audit.

(Comment 86) One comment asserted that we seem to be requiring that tissue be sterile and that decontamination processes be validated to produce tissue that is not contaminated or is sterile. The comment asserted that viable tissue cannot be made sterile and that reducing bioburden is not the same as eradicating contamination.

(Response) FDA is not requiring at this time that tissue be sterile, but we do expect aseptic techniques to be used during manufacturing to prevent contamination and cross-contamination. Indeed, it is the current industry practice to use aseptic techniques during recovery and processing. Whenever an activity is used in the processing of HCT/Ps, that activity must be controlled to limit the introduction of disease agents. When technology progresses to the extent that viral clearance or sterilization is feasible, FDA may revise these CGTPs to require that HCT/Ps be sterile. FDA welcomes submissions as to when technology will have progressed to this point.

(Comment 87) One comment on proposed § 1271.220(a) requested clarification of the term ''manufacturing process.''

(Response) We have re-examined our use of the phrase ''manufacturing process'' in § 1271.220(a) and have concluded that it is confusing. Processing is one of the steps in manufacture, as defined in § 1271.3(e). Because §§ 1271.220, 1271.225, and 1271.230 pertain only to processing, rather than to the other steps in manufacture, we have replaced ''manufacturing process'' with ''process.''

(Comment 88) We received five comments on proposed § 1271.220(b), which addressed processing materials. Two comments noted that it is not always possible to document that a processing material has been removed from an HCT/P, and that validated procedures should be sufficient. One comment proposed the use of published data and industry practice to determine whether a processing material or its residues may elicit an adverse reaction. This comment also recognized that product labeling may be used to warn potential users with respect to the possible presence of residues.

(Response) We have removed proposed paragraph (b) in its entirety from § 1271.220 and renumbered the paragraphs accordingly.

Pooling.

Proposed § 1271.220(c) states that human cells or tissues from two or more donors shall not be pooled (placed in physical contact or mixed in a single receptacle) during manufacturing. We noted that commingling of cells or tissues from a single infected donor with cells or tissues from other donors could contaminate the entire pooled quantity, greatly increasing the risk of exposure to infectious agents to recipients of the pooled materials (66 FR 1508 at 1516). Proposed paragraph (c) has been renumbered as (b).

(Comment 89) Approximately six comments agreed with the proposed prohibition on pooling. Several comments pointed to an increased risk of infectious disease transmission associated with pooling, and asserted that pooling could increase the threat of previously unknown transmissible diseases. One comment asserted that there is a particularly high risk for Rh-negative women of childbearing age who receive tissue from Rh-positive donors. Two comments argued that pooling would impair the effectiveness of tissue recalls, because tracing to the source of a problem would be impossible. Comments also questioned the efficacy of processes used to manufacture pooled HCT/Ps and noted that no process entirely eliminates the risk of infectious disease transmission. Two comments asserted that pooling would be distasteful to donors and their families.

(Response) These comments raise valid concerns. We agree in particular with the concerns expressed about the increased risk of communicable disease transmission and the difficulty of tracking pooled HCT/Ps.

(Comment 90) Approximately 10 comments opposed our proposal to prohibit the pooling of cells or tissues. Several comments argued that the proposed regulation is too restrictive and could stifle new technologies.

(Response) Although we are aware of promising new technologies that involve the pooling of cells from two or more donors, we remain concerned about the infectious disease risks inherent in pooling. On June 26, 2002, FDA consulted the Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) about the validation of procedures to prevent contamination and cross-contamination of HCT/Ps by TSE agents. At this meeting, speakers presented information on the three approaches that could be taken to reduce the risk of TSE transmission:

- Careful screening of the donor for TSE and risk factors for TSE;
- Control of the recovery and processing of cells and tissues to prevent contamination and cross-contamination; and
- Use of steps during processing to remove or inactivate any TSE agents that may be present.

One of the processing controls discussed was the use of single donor aseptic recovery and processing, rather than a process that would involve pooling of cells or tissues from two or more donors. When asked about specific measures and controls appropriate to prevent TSE agent transmission (e.g., single donor aseptic processing), the committee voted unanimously that single donor processing should be considered the gold standard, but that a pooled process may be appropriate under certain circumstances with adequate controls. The committee members did not discuss which circumstances and what controls would be adequate.

Under § 1271.155, an establishment may submit a request for an alternative or exemption from the prohibition from pooling provided that it has data showing that the processing method adequately addresses the risks associated with pooling.

(Comment 91) Two comments opposed our assertion that commingling cells or tissues from different donors, who have been screened and tested, would increase the risk to recipients of exposure to infectious agents.

(Response) We disagree with these comments. Screening and testing of donors, although crucial, does not completely eliminate infectious disease risk, for several reasons. The donor may be in the ''window period'' during which he or she may be infectious (i.e., have viral marker levels that are below detection by current tests). Chronic carriers of a disease may be immuno-silent; i.e., they do not mount an antibody response. In addition, laboratory errors may be made, or an HCT/P may be released improperly. Moreover, current tests may not detect all genetic variants of a particular virus, or a donor may be infected with an ''emerging infectious disease,'' for which screening measures or tests have not been developed. Finally, there may be questions about the accuracy of current tests that are not approved by FDA for use with cadaveric specimens and about the reliability of donor histories obtained from another person

(not the donor). Each of these risks is small, and presents a small chance of leading to communicable disease transmission to a single HCT/P recipient. However, the risk is magnified when HCT/Ps from different donors are pooled during manufacture. Information provided at the TSEAC meeting described previously showed that the risk of exposing a recipient to an infectious disease agent contained in a pool, where one or more units in the pool were recovered from an infected donor, is directly proportional to the prevalence of the agent in the donor population and the size of the pool.

(Comment 92) Several comments pointed out benefits of pooling. Two comments pointed to the need for pooling to obtain a sufficient dose of an HCT/P, especially in adults (e.g., from cord blood). One comment stated that pooling contributes to product consistency and uniformity.

(Response) We are retaining the prohibition on pooling during manufacturing in § 1271.220(b). We continue to believe that, in general, the risks of pooling HCT/Ps (increased risk of communicable disease transmission) outweigh the benefits of pooling. For some biological products, e.g., plasma derivatives, the benefits of pooling outweigh the risks. In the case of plasma derivatives, pooling contributes to product consistency. In fact, 21 CFR 640.102(d) requires that material from not less than 1,000 donors be pooled to make immune globulin. For plasma derivatives, it is necessary to pool plasma from many donors to obtain an adequate amount of product to treat one recipient (i.e., a sufficient dose). In addition, pooling plasma may dilute the viral burden or provide neutralizing antibodies that may inactivate any virus present in the pool. However, these benefits of pooling do not apply, in general, to the pooling of HCT/Ps from many donors. For instance, tendons from different donors would not need to be pooled to provide consistency or to obtain a sufficient dose. Neither would bones pooled from different donors provide neutralizing antibodies to inactivate any virus present in the pool, since neutralizing antibodies are present in plasma. In the case of cord blood, most of the plasma is removed during processing, so that pooling of cord blood from different donors would not provide sufficient neutralizing antibodies to neutralize any virus present in the pool. Furthermore, when cord blood units from more than one donor are administered to an adult recipient to obtain a sufficient dose, the units are generally given sequentially and are not pooled.

In order for us to determine whether any benefits to pooling HCT/Ps from different donors outweigh the risks in a particular case, we would need additional data. Such data may be submitted and evaluated under a request for an alternative or exemption in § 1271.155.

(Comment 93) Several comments asserted that the risks of pooling could be mitigated through validated procedures for clearing pathogens or sterilizing the pooled HCT/Ps. One of these comments suggested additional regulatory language that would permit pooling where it is necessary and does not create an unreasonable risk of communicable disease transmission. Another comment proposed that the final rule should allow the pooling of stem cell products from two or more donors, as long as the resulting pooled product is transplanted into only one recipient.

(Response) We agree that, in some instances, it may be appropriate to assess the risks and benefits of pooling. Such assessment could be submitted under § 1271.155 in a request for an exemption or alternative to the prohibition on pooling in § 1271.220(b). However, we decline to modify the proposed regulation as suggested and, for the reasons explained in Comments 89 through 92, we have retained the general prohibition on pooling.

(Comment 94) One comment that supported proposed § 1271.220(c) asserted that no waivers or exceptions should be allowed that would permit pooling.

(Response) We disagree with this comment. Although we remain very concerned about the communicable disease risks associated with pooling, we do not rule out the possibility that pooling may be appropriate in some specific situations. We will consider requests for exemptions from or alternatives to § 1271.220(b) under the provisions of § 1271.155. At the June 2002 TSEAC meeting described previously, the committee members supported the possibility that exemptions from the proposed pooling prohibition might be appropriate, but did not discuss criteria upon which to grant such an exemption.

In-process control and testing.

Proposed § 1271.220(d) would require procedures to ensure that specified requirements for in-process HCT/Ps are met. These procedures must ensure that an in-process HCT/P is controlled until the required inspection and tests or other verification activities have been completed or necessary approvals are received and documented. In addition, sampling of in-process HCT/Ps must be representative of the material to be evaluated.

There were no comments on this provision, which has been renumbered paragraph (c). We have revised this paragraph to cover in-process control and testing. Paragraph (c) requires you to ensure that specified requirements, consistent with paragraph (a) of this section, for in-process controls are met, and that each in-process HCT/P is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received and documented. Sampling of in-process HCT/Ps must be representative of the material to be evaluated.

We note that paragraph (c) includes the prevention of bacterial and other contamination. Compliance with this paragraph requires checking the results of testing at various steps in processing (for example, by sampling in-process HCT/Ps). The sample selected for testing (e.g., culture) must be representative of the entire HCT/P. This may not be the case if a small snip of the HCT/P or companion tissue (i.e., tissue adjacent to the HCT/P that is processed along with the HCT/P) is cultured. The MMWR cited in section III.C.1 of this document recommended that performing both destructive (i.e., performed on tissue that had been ground up) and swab cultures (of the tissue surface) should be considered (Ref. 1).

Dura mater.

Proposed § 1271.230(c) would require dura mater to be processed using a validated procedure that reduces TSE while preserving the clinical utility of the product. We have moved proposed § 1271.230(c) to § 1271.220(d) because it relates more closely to processing and process controls than to process validation.

(Comment 95) Three comments objected to proposed § 1271.230(c). One comment urged us to eliminate the provision, because FDA should not endorse the concept of an acceptable level of TSE risk, and another comment asserted that there is no acceptable level of TSE contamination. Another comment opined that the proposed rule is arbitrary because FDA has not validated methods for decontaminating tissue contaminated with prions.

(Response) We disagree that FDA is endorsing the concept of an acceptable level of TSE risk. The donor-eligibility rule requires screening of all HCT/P donors for TSE risk factors and testing of dura mater donors (see §§ 1271.75(a) and 1271.85(e)). In this rule, we are requiring additional processing safeguards to reduce the level of the TSE agent that may be present in dura mater,

even after a donor has been determined to be eligible based on screening and testing. Taken together, these requirements are intended to help prevent the transmission of TSE by dura mater and should by no means be considered to endorse an acceptable level of risk. Eliminating proposed § 1271.230(c) would decrease the safeguards in place and elevate the risk; we decline to take this step.

We disagree that the requirement to use a validated procedure is arbitrary or that it is necessary for FDA to validate procedures for the removal of the TSE agent in human tissue. TSEAC has recommended treating human dura mater with sodium hydroxide (June 26, 2002), and in the preamble to the proposed rule we cited a sodium hydroxide (NaOH) protocol as an example of a validated procedure (66 FR 1508 at 1517). The TSEAC recommendation was based on a study in an animal model, in which 1.0N NaOH treatment reduced Creutzfeld Jakob Disease (CJD) infectivity (Refs. 2, 3, and 4). However, we realize that this method is not being used for reducing TSE infectivity in human dura mater distributed at this time, and that there are no other validated methods currently available. Although 1.0N NaOH treatment reduces infectivity, this process can also decrease the clinical utility of the dura mater. Therefore, § 1271.220(d) requires use of a published validated process when one becomes available.

As new validated processes become available, they will be published in the literature. You do not have to validate the published procedure; rather you must verify that the previously validated process has been fully and properly implemented in your establishment. We recognize that processing methods may be developed that reduce the risk of TSE but that render the HCT/P no longer useful for its purpose. Accordingly, you are not required to implement a process if it adversely affects the clinical utility of the dura mater. Alternatively, you may validate an equivalent procedure for use in your establishment that is at least as effective as the published procedure, without adversely affecting the clinical utility of the dura mater.

We recognize that, due to a variety of circumstances, you may not be aware when there is a published, validated process that reduces the risk of TSE. We intend to follow the good guidance practices set out in 21 CFR 10.115 to advise you when we have identified the existence of a published, validated process that reduces the risk of TSE, and we would ordinarily solicit public comment before issuing a final guidance.

12. Process Changes (§ 1271.225)

Proposed § 1271.225 would require the establishment to establish and maintain procedures for making changes to a process. Such changes would be verified or validated, and approved by a responsible person before implementation. We have removed from § 1271.225 the requirement that establishments have procedures for making process changes.

(Comment 96) One comment asserted that this section does not apply to eye banks and that they should not be required to comply. Another comment from an eye bank stated that the section is too broad and should be narrowed.

(Response) Section 1271.225 applies to establishments engaged in the processing of HCT/Ps, including eye banks that perform processing activities. For example, a switch from one brand of storage solution to another would be a process change. In this situation, the eye bank must verify that the new process performs as intended in a manner that does not introduce, transmit, or spread communicable disease agents.

Under § 1271.150(b), an establishment need only comply with those requirements applicable to the operations in which it engages (§ 1271.150(b)). Thus, if you are an establishment that does not engage in the processing of HCT/Ps, you do not need to comply with § 1271.225. We have discussed the meaning of ''processing'' at Comment 20. We disagree that it is necessary to narrow the provision, which is intended to apply to the full range of HCT/P establishments engaged in processing.

(Comment 97) One comment on proposed § 1271.225(a) asserted that most, but not all, changes will need to be verified or validated. As examples of simple changes that should not require verification or validation, the comment cited requirements for additional training or changes in location or storage of records. The comment suggested that we add the phrase ''if appropriate as determined by a risk assessment.''

(Response) Under § 1271.225, if you are an establishment engaged in the processing of HCT/Ps, you are required to verify or validate any change to a process, to ensure that the change does not create an adverse impact elsewhere in the operation. The examples cited by the comment are not examples of process changes.

(Comment 98) Proposed § 1271.225(b) contained requirements for maintaining change records. One comment agreed that records of the rationale for each change should be maintained, calling this requirement a real time saver. Another comment asserted that § 1271.225(b) is more stringent than the comparable requirement for blood.

(Response) We have removed the requirement for documenting all changes to an established process and the rationale for such a change. We have maintained the proposed requirement for communicating approved changes to appropriate personnel in a timely manner; however, it no longer appears in paragraph (b), which has been deleted.

13. Process Validation (§ 1271.230)

Where the results of a process cannot be fully verified by subsequent inspection and tests, proposed § 1271.230 would require the process to be validated and approved according to established procedures. The validation activities, results, and the date and signature of the individual approving the validation would be documented. Re-validation would be required where appropriate in the case of changes to a validated procedure.

We have revised § 1271.230. Paragraph (a) now refers to processing described in § 1271.220. Paragraph (b) now refers to written representations, rather than claims, and is more limited than proposed. Paragraph (c) on dura mater is now § 1271.220(d). Paragraph (d) requiring procedures for the monitoring and control of validated processes has been deleted. For clarity, we have deleted the word ''deviations'' from proposed § 1271.230(e), now § 1271.230(c); that paragraph now refers only to changes to a validated process.

(Comment 99) Several comments asserted that the requirement for process validation in proposed § 1271.230 does not apply to eye banking. One comment cited the use of annually validated mechanical devices used in processing eye tissue and the evaluation of tissue by trained personnel.

Another comment asserted that the rule is vague as to which processes a company should validate and approve and how the validation and approval should be conducted. This comment further asserted that the rule fails to take into account the unique biological characteristics of the various human cell and tissue types (e.g., musculoskeletal tissue).

(Response) We have carefully worded § 1271.230 to take into account the uniqueness of various HCT/Ps. Thus, § 1271.230(a) requires validation of a process where the results of processing described in § 1271.220 cannot be fully

verified by subsequent inspection and tests. Rather than being vague, this language recognizes that an establishment has specific knowledge of the HCT/Ps it manufactures, including when verification activities will suffice and when process validation is required because results cannot be fully verified. We agree that the control and results of the processes performed at eye banks may be able to be achieved through verification activities; in this case, validation would not be required.

(Comment 100) One comment asserted that the documentation of eye and tissue banking successes in medical literature should constitute sufficient objective evidence for procedures that have been in use for years and that documentation of meeting predetermined specifications should only be required for new procedures that are not consistent with pre-existing standards and practices.

(Response) We disagree. Medical literature alone is insufficient to verify or validate the processes performed at a specific establishment. Each establishment that performs steps in the processing of HCT/Ps must demonstrate that it has validated or verified a given process at that particular establishment and that it is capable of controlling that process. These steps must be taken for all processes conducted by an establishment, regardless of when the process was initiated or how long the process has been in place.

(Comment 101) Proposed § 1271.230(a) states, in part, that where the results of a process cannot be fully verified by subsequent inspection and tests, the process shall be validated and approved according to established procedures. Two comments recommended deleting the word ''fully'' from this provision, arguing that it is too broad and could be subject to inconsistent application. These comments asserted that, once a process has been validated, if changes are required that do not increase the risk of communicable disease transmission to the recipient, a written justification for not revalidating should be sufficient.

(Response) We disagree with the comments' suggestion to delete ''fully.'' The term ''fully verified'' has been used with respect to process validation in ISO standards for years. Moreover, the term is used in the QS regulation on process validation applicable to medical devices (§ 820.75(a)).

The MMWR discussed at III.C.1 of this document cited CDC concerns with bacteriostasis (i.e., the arrestment or inhibition of bacterial growth and reproduction) (Ref. 1). The report surmised that because tissues later implicated in patient deaths were cultured only after suspension in an antibiotic/antifungal solution, residual antibiotics on the tissues might have caused a false-negative culture result because of bacteriostasis. Undetected organisms in stasis can later multiply (e.g., once an HCT/P has been transplanted into a patient and the residual antibiotic is metabolized so that it no longer inhibits growth of the bacteria). Therefore, we recommend that a validated microbiological culturing process include bacteriostatic and fungistatic testing.

In accordance with § 1271.150(e) (''where appropriate''), we agree that an assessment with written justification for not revalidating a change to a validated process would be sufficient under § 1271.230(c) if the establishment can show that the change does not increase the risk of communicable disease transmission to the recipient.

(Comment 102) Proposed § 1271.230(b) states, in part, that any process-related claim in labeling or promotional materials, e.g., a claim for sterility or viral inactivation, must be based on a validated process. One comment asked why, if verification is performed on each and every finished product, this could not be claimed in labeling. Three comments asked us to allow sterility claims based on verification rather than validation when technology limitations exist and when established manufacturing approaches have not led to clinical problems.

(Response) We agree with these comments and have modified § 1271.230(b) to include verification as well as validation. That paragraph now requires that any written representation that your processing methods reduce the risk of transmission of communicable disease by an HCT/P, including but not limited to a representation of sterility or pathogen inactivation of an HCT/P, be based ''on a fully verified or validated process.''

(Comment 103) One comment suggested deleting claims for sterility or viral inactivation from proposed § 1271.230(b) and creating a new paragraph that specifically addresses the validation of processes intended to achieve sterility or viral clearance.

(Response) We decline to make this change. Providing specific methods for validation or verification of processes is not within the scope of this rulemaking. However, we have narrowed paragraph (b) so that it no longer covers ''any process-related claim,'' but now is limited to any written representation that your processing methods reduce the risk of transmission of communicable disease by an HCT/P, including but not limited to, a representation of sterility or pathogen inactivation of an HCT/P.

14. Labeling Controls (§ 1271.250)

Proposed § 1271.250 would require procedures to control the labeling of HCT/Ps, designed to ensure proper product identification and prevent mixups. These procedures would include verification of label accuracy, legibility, and integrity; they would further ensure that each HCT/P be labeled in accordance with all applicable requirements.

We have reorganized this section into three paragraphs for clarity and have corrected the cross-references to labeling requirements in part 1271.

Two comments supported this section as consistent with industry standards applicable to eye banking.

(Comment 104) One comment criticized as burdensome the proposed requirement for procedures to ensure that each product made available for distribution is accompanied by documentation of the donor eligibility determination as required under § 1271.55. This comment asserted that, if the product is going from the laboratory to the clinical unit of the same program, detailed documentation of donor testing does not need to accompany the HCT/P, as it can be found in the laboratory. According to the comment, such documentation of testing only makes sense if distribution means distribution outside of the institution.

(Response) We disagree with this comment. As discussed at Comment 17, distribution includes the intracompany shipment of a finished HCT/P; e.g., the release of an HCT/P from a collection/processing facility to an operating room in the same facility. Similarly, the release of an HCT/P from a laboratory to the clinical unit of the same program is distribution, and the HCT/P must be accompanied by the documentation required by § 1271.55. We have modified § 1271.55 in the donor-eligibility final rule (69 FR 29786 at 29831) to remove the requirement that an HCT/P be accompanied either by the relevant medical records or a summary of those records; that section now requires HCT/Ps to be accompanied by a distinct identification code, a statement of whether or not the donor has been determined eligible, and a summary of the records used to determine donor eligibility. This requirement is not burdensome. Moreover, it is very important that the administering physician have in hand specific and accurate information about the HCT/P; availability of the

documentation in another part of a facility is insufficient.

(Comment 105) One comment asserted that the type of information called for is exorbitant for the identification of individual transplant products. This comment requested that the rules be streamlined along the lines of industry standards that provide for coded identification of donor, identification of intended recipient, and critical information regarding donor eligibility and type of processing used.

(Response) We disagree that the labeling information required by these rules is excessive. A review of the industry standards cited by the comment indicates that they specify the same information as required by these regulations, as well as additional information not required under these regulations; e.g., the identification of intended recipient, the type of processing used (Foundation for the Accreditation of Cellular Therapy (FACT) 2002; American Association of Blood Banks (AABB) 2002).

15. Storage (§ 1271.260)

Proposed § 1271.260 would require each establishment to control its storage areas and stock rooms to prevent mixups, commingling, deterioration, contamination, and cross-contamination of HCT/Ps and supplies, and to prevent improper release for distribution. The establishment would also be required to store the HCT/Ps at an appropriate temperature, assign an expiration date for the HCT/P where appropriate, and take and document corrective action when indicated.

One comment supported this section as proposed.

(Comment 106) We received several comments on the storage temperature and period requirements in proposed § 1271.260(b). Some comments asked whether establishments must validate storage temperatures and periods, and noted that many of these have been established by the tissue industry based on experience. Another comment cited specific industry standards for eye banks. One comment asserted that the proposed parameters for setting storage temperature may not be optimal at the same temperature.

(Response) Voluntary standards issued by professional organizations exist for many aspects of these regulations, and we agree that establishments may follow these established industry standards where the standards meet the requirements set forth in this section. However, these standards may only apply to specific HCT/P types (e.g., corneas) and, moreover, are not always sufficiently comprehensive to include all of the requirements in this rule. Alternatively, establishments may establish and validate their own criteria for storage temperature and storage period, as determined for specific HCT/Ps stored in their facilities.

The regulation (§ 1271.260(b)) now requires storage at an appropriate temperature. Section 1271.260(e)) requires you to establish acceptable temperature limits to inhibit the growth of infectious agents.

(Comment 107) Proposed § 1271.260(c) would require establishments to assign expiration dates to their HCT/Ps, where appropriate. Two comments stated that the safe duration of cryopreservation for hematopoietic stem/progenitor cells is unknown and will take years to validate.

(Response) The requirement for establishing an expiration date is qualified by the term, ''where appropriate.'' Section 1271.150(e) explains that a requirement is ''appropriate'' unless an establishment can justify otherwise, and maintains documentation of that justification. We consider it appropriate to assign expiration dates for ''fresh'' (i.e., noncryopreserved) HCT/Ps, and for those HCT/Ps that are thawed after cryopreservation and storage. If such applicable expiration dates have been established by industry or medical practice and meet the requirements of this section, you may use those dates for your HCT/Ps, whether ''fresh'' or cryopreserved. If scientific data do not exist for establishing expiration dates, then no expiration date is required at this time. We encourage the industry to perform studies to establish expiration dates for those HCT/Ps that currently do not have expiration dates.

We have modified § 1271.260(c)(2) to refer to ''processing,'' rather than ''processing procedures,'' to avoid redundancy.

16. Receipt, Predistribution Shipment, and Distribution of an HCT/P (§ 1271.265)

Proposed § 1271.265 would require establishments to establish and maintain procedures for receipt, acceptance or rejection, distribution, and destruction or other disposition of HCT/Ps; and document these activities.

Several comments supported proposed § 1271.265. One comment indicated that the provisions are worthwhile, and another comment supported documenting the identity of the consignee.

We have reorganized § 1271.265. Paragraphs (a) through (d) now contain substantive requirements with respect to receipt, predistribution shipment, distribution, packaging and shipping. Each of these is a core CGTP requirement. Paragraph (e) requires you to establish and maintain procedures for activities under paragraphs (a) through (d) and to document these activities. (This documentation must include, for example, the identification of the HCT/P; in this rule we have specified that you must also document the establishment that supplied the HCT/P (e.g., by maintaining receipt records).) Paragraph (f) relates to returns to inventory, as proposed.

(Comment 108) One comment asked for clarification to ensure that all donated materials are subject to § 1271.265, regardless of their processing status.

(Response) We agree that all donated materials are subject to this section. The definition of HCT/P covers cells and tissues at all stages of manufacture, from recovery through distribution (66 FR 5447 at 5448).

Although we do not believe it is necessary to modify § 1271.265 as suggested by the comment, we have made a related change, by adding a new provision on ''pre-distribution shipment'' (§ 1271.265(b)). This change is necessitated by our revision of the definition of ''distribution,'' discussed at Comment 17, to refer to the conveyance or shipment of an HCT/P that has been determined to meet all release criteria. Predistribution shipment includes, for example, shipment of an HCT/P within your establishment or to another establishment, or shipment from an establishment that recovers cells or tissue to an establishment that packages them.

Section 1271.265(b) states that if you ship an HCT/P within your establishment or between establishments (e.g., procurer to processor) and the HCT/P is not available for distribution as described in paragraph (c) of this section, you must ship the HCT/P in quarantine.

(Comment 109) Proposed § 1271.265(b) would require each incoming HCT/P to be inspected according to established procedures. Two comments on proposed § 1271.265(b) asked if it is sufficient to inspect a shipping container for physical damage, or if the containers must be opened.

(Response) You should tailor your acceptance procedures to the specific HCT/P and circumstances. As the comments point out, in some instances opening a sealed shipping container could potentially damage an HCT/P. In

designing your acceptance procedures, you should take into account this possibility, as well as alternate ways of inspecting the HCT/P (e.g., inspection of container, ensuring proper temperature has been maintained during transit). If, after receiving the HCT/P, you hold it in storage, your storage conditions must comply with § 1271.260.

The MMWR cited at section III.C.1 of this document recommended that, to minimize the potential of bacterial contamination, tissue should be cultured before suspension in antimicrobial solutions, and if bacteria are isolated, all tissue from the same donor should be discarded if it cannot be sterilized (Ref.1). Where appropriate, your acceptance procedures should include tests and should spell out criteria for rejecting incoming HCT/Ps. Preprocessing cultures may be appropriate in some situations.

(Comment 110) One comment on proposed § 1271.265(c) (availability for distribution) asserted that ''deterioration'' is vague and open to interpretation.

(Response) By ''deterioration,'' we mean decay or decomposition. However, in response to Comment 9 we have removed references to ''deterioration'' from the CGTPs, including § 1271.265.

(Comment 111) One comment on proposed § 1271.265(c) asserted that the requirements for making an HCT/P available for distribution should not apply to distributors themselves.

(Response) The requirements in § 1271.265(c) are intended to apply to the establishment that first makes an HCT/P available for distribution (defined in § 1271.3(z)). This establishment, which may or may not be the actual distributor, needs to have procedures in place under § 1271.265(e) for determining that an HCT/P may be made available for distribution, including release criteria designed to prevent communicable disease transmission. The regulation specifies that you must not make available for distribution any HCT/P that is in quarantine, is contaminated, is recovered from a donor who has been determined to be ineligible or for whom a donor-eligibility determination has not been completed (except as provided under §§ 1271.60, 1271.65, and 1271.90), or that otherwise does not meet release criteria designed to prevent communicable disease transmission. Release criteria include criteria for releasing a product under § 1271.60, § 1271.65, or § 1271.90 that ensure, among other things, that the conditions for such release are met and that the HCT/P is labeled with the warnings required by the regulations.

(Comment 112) Proposed § 1271.265(d) would require packaging and shipping containers to be designed, validated, and constructed to protect the HCT/P from contamination during customary conditions of processing, storage, handling, and distribution. The final rule requires that packaging and shipping containers protect HCT/Ps from contamination.

Three comments on proposed § 1271.265(d) suggested that verification of packaging containers is more appropriate than validation.

(Response) We agree that either validation or verification may be appropriate ways of ensuring the adequacy of packaging and shipping containers. Please note, however, that the final rule has been revised so that it does not require either verification or validation of packaging and shipping containers.

(Comment 113) Proposed § 1271.265(e) would require that appropriate shipping conditions be defined for each type of product to be maintained during transit. One comment questioned whether shipping conditions must be defined for each type of graft (e.g., femur ring, bone powder) or for each type of tissue (freeze-dried bone).

(Response) The final rule renumbers this provision as § 1271.265(d), combines it with the provision on packaging, and provides each establishment with the flexibility to determine whether to establish shipping conditions for each type of graft or for each type of tissue. Either approach may be appropriate.

(Comment 114) One comment on proposed § 1271.265(f) stated that the requirement to establish procedures for returning HCT/Ps to inventory is not applicable to all HCT/Ps.

(Response) We agree that some establishments may not engage in all activities covered by the CGTPs. Under § 1271.150(c), establishments need only comply with the requirements that are applicable to the operations in which they engage. Thus, an establishment that does not return HCT/Ps to inventory is not required to establish procedures for that activity.

17. Records (§ 1271.270)

Proposed § 1271.270 would require establishments to maintain records concurrently with the performance of each significant step required in subparts C and D. A records management system would be established and maintained. Records would be maintained: Electronically, as original paper records, or as true copies; 10 years after their creation; and for contracts, agreements, and other arrangements with another establishment to perform a step in manufacturing. One comment from a professional organization supported the goal of this provision, which it identified as chain of custody.

(Comment 115) One comment on § 1271.270(b) asserted that maintaining records organized by product type is not practical and that it is more useful to organize records by donor. Another comment asserted that detailing how to organize records is an unnecessary intrusion and that the example given was unduly complicated.

(Response) In response to the first comment, we have deleted the words ''of each type'' from the third sentence of § 1271.270(b), so that it now reads: ''Records pertinent to the manufacture of HCT/Ps * * * must also be maintained and organized under the records management system.'' In response to the second comment, we note that, although paragraph (b) requires you to establish and maintain a records management system, it does not specify the details of such a system. It is the responsibility of the establishment to organize its records in a useful manner. The example given in the preamble to the proposed rule was intended simply to explain, to those unfamiliar with the term, what is meant by a ''records management system'' (66 FR 1508 at 1518). We have revised paragraph (b) so that the requirement for a records management system applies only to core CGTP requirements.

(Comment 116) We received two comments on the requirement in proposed § 1271.270(c) that information on the identity and relevant medical records of a donor must be in English or, if in another language, must be translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

(Response) Proposed paragraph (c) of § 1271.270 would relate to the donor-eligibility requirements in subpart C of part 1271. In the donor-eligibility final rule (69 FR 29786 at 29831), we incorporated the contents of proposed § 1271.270(c) into the records requirements in § 1271.55 and responded to these comments. We are now removing proposed paragraph (c) from § 1271.270.

(Comment 117) Proposed § 1271.270(e) would require records to be kept for 10 years. We specifically requested comments on whether there are specific types of record for which retention period shorter than 10 years

would be appropriate (66 FR 1508 at 1518).

Two comments responded that a 10-year record retention is appropriate, and one of these comments cited an industry standard requiring records to be maintained 10 years.

(Response) We have maintained the 10-year record retention requirement for all records. Proposed § 1271.270(e) has been renumbered § 1271.270(d).

(Comment 118) Three comments pointed out that the record retention requirement in proposed § 1271.270(e) is confusing, and each of these comments suggested new language. One suggestion would require that the establishment retain records for 10 years after transplantation, or after expiration if transplant date is unknown. Two comments suggested that we require the retention of records for a minimum of 10 years after creation, 10 years after the expiration of a HCT/P, or 10 years after the appropriate disposition of dura mater.

(Response) We have revised proposed paragraph (e) by replacing the words ''implantation, transplantation, infusion, or transfer'' with ''administration.'' The second sentence of § 1271.270(d) now reads

However, you must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest.

(Comment 119) Proposed paragraph (e) would require an establishment to make provisions for all records to be maintained for the required period in the event that the establishment ceases operation. One comment asserted that it is not practical for an establishment to retain records if it has gone out of business.

(Response) We encourage you to make provisions for keeping records in the event that your establishment goes out of business, because some communicable disease have very long incubation periods before symptoms appear (e.g., CJD). However, because of difficulties in enforcing the proposed requirement, we have removed it from the final regulation.

18. Tracking (§ 1271.290)

Proposed § 1271.290 would require each establishment that performs any step in manufacturing to set up a system for tracking each HCT/P so that the HCT/P may be tracked from donor to recipient and recipient to donor.

We have clarified that tracking requirements apply to those facilities that handle the HCT/P. If you do not handle the HCT/P (e.g., you are the testing laboratory that receives a blood specimen, but you do not actually handle the HCT/P), you do not have to participate in the tracking requirements.

We have also added language to clarify that the purpose of a tracking system is to facilitate the investigation of actual or suspected transmission of communicable disease and any appropriate and timely corrective action.

Finally, we have revised the tracking provisions to require a system that enables tracking to and from the consignee, rather than to and from the recipient, and have added that labeling includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor.

(Comment 120) We received several comments in support of the proposed requirements. One comment responded to our request for comments from establishments that have already developed and implemented tracking systems about the success or failure of those systems (66 FR 1508 at 1519). This comment described its successful tracking system and noted that tracking fulfills its ongoing responsibility to the patients who have received its tissues. The establishment provides hospitals with peeloff labels that identify each unique product and the bank that provided it, and also with tracking logs for the hospitals to use to control inventory. Information on the use of the HCT/P is returned to the tissue bank by the hospital in a self-addressed envelope and then entered into the establishment's database. The establishment sends regular reminders to hospitals notifying them of tissue for which it has not received transplant records. The comment noted that hospitals willingly participate, and it cited a high (85 to 100 percent) return of transplant records.

(Response) We appreciate this detailed information and believe it demonstrates both the feasibility and the importance of developing a functioning tracking system.

(Comment 121) Two comments argued that the proposed requirements could not be justified based on risk and were inconsistent with industry standards. The comments also asserted that the proposed tracking requirement would require collection of confidential patient information in conflict with privacy regulations issued under the Health Insurance Portability and Accountability Act (45 CFR parts 160 and 164). Those regulations were finalized on December 28, 2000 (65 FR 82462), and amended on August 14, 2002 (67 FR 53182).

(Response) We disagree. Not only are these requirements justified by the communicable disease risks posed by HCT/Ps, but they are consistent with industry standards. AATB standards require traceability and dispensing records by the tissue dispensing service (medical, dental, hospital facility, physician's office) (See the American Association of Tissue Banks (AATB) Standards 2002, L4.000). The Eye Bank Association of America (EBAA) medical standards require that recipient identification readily traceable to each unique graft number be retained in the eye banks' records (See EBAA Medical Standards 2002, M1.400).

The proposed tracking requirements are not inconsistent with the HIPAA privacy regulation, which sets up protections for individually identifiable health information. The privacy rule applies only to ''covered entities'': e.g., health plans, health care clearinghouses, and health care providers conducting certain transactions in electronic form (45 CFR 164.104). HCT/P establishments subject to the tracking requirements are unlikely to meet the definition of a covered entity. Thus, the privacy regulation would not apply to their activities, and the use in product tracking of a distinct identification code by an entity that is not covered by that rule would not be subject to the privacy rule.

In the unusual event that an establishment met the definition of covered entity, the establishment's disclosure of individually identifiable health information would be subject to the privacy rule. However, the privacy rule allows covered entities to share de-identified health information for any purpose and includes requirements for determining whether information is de-identified. (45 CFR 164.502(d), 164.514(a)-(c)). Further, a covered entity may assign a code to otherwise de-identified data, if the code is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, and if the covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for reidentification (45 CFR 164.514(c). Thus, an establishment that is a covered entity is not in violation of the privacy rule if it discloses information de-identified in accordance with 45 CFR 164.514(a)-(c), including a distinct identification code that meets the requirements of 45 CFR 164.514(c).

Consignees are likely to meet the definition of a covered entity, and would therefore be covered by the privacy rule. However, the tracking provision does not require consignees to provide individually identifiable health information; it requires only that establishments be able to track HCT/Ps to consignees.

We note that a consignee may on occasion wish to disclose protected health information to an establishment. For example, a consignee may wish to report to the establishment that a recipient of an HCT/P developed an infection at the site of the transplant. Under the public health activities provisions of the privacy rule, the rule permits, but does not require, entities that meet the definition of a covered entity to disclose protected health information to persons subject to the jurisdiction of FDA with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity (45 CFR 164.512(b)(1)(iii)). The rule specifically identifies tracking FDA-regulated products as a purpose permitting such disclosures, along with collecting and reporting adverse events and enabling product recalls, repairs, replacement, or lookback (45 CFR 164.512(b)(1)(iii)(A), (b)(1)(iii)(B), and (b)(1)(iii)(C)). Finally, in the event that one of the previously mentioned provisions is not applicable, covered entities may disclose protected health information pursuant to an authorization from the individual or the individual's personal representative (45 CFR 164.502(g)(1) and 164.508). We further discuss the applicability of the privacy rules in the context of donor eligibility in Comment 4 to the donor eligibility rule (69 FR 29786 at 29790).

(Comment 122) One comment suggested that the regulations should refer to ''tracing'' instead of ''tracking,'' to avoid confusion with device tracking.

(Response) We disagree. The term ''tracking'' adequately defines the operations being performed with respect to the HCT/P and is a term that is recognizable by industry.

(Comment 123) Several comments from eye banks asked for an exception for corneas that are distributed internationally, noting the difficulty of obtaining information on recipients. One of these comments asked that the consignee's signature and intended disposition be acceptable.

(Response) We decline to grant an exception for corneas that are distributed internationally. However, we note that the tracking requirements in § 1271.290 do not require tracking to the recipient level, but rather to the consignee. In the case of international distribution, obtaining the consignee's signature and intended disposition is acceptable.

(Comment 124) Two comments asserted that it would be impossible to comply with proposed § 1271.290 unless all establishments adopt a uniform tracking method, and further opined that many vendors may elect not to participate in tracking due to the potential disclosure of proprietary information.

(Response) We disagree with these comments. We prefer to provide establishments with flexibility in complying with § 1271.290, and for that reason we decline to mandate a uniform tracking method. It is unclear why it would be impossible to comply with the requirement in the absence of uniformity. It is also unclear what proprietary information would be disclosed via a tracking system. However, we note that each establishment has the choice of maintaining its own tracking method or participating in the system developed by another establishment; a vendor who shares the concerns expressed by these comments may choose not to participate in another establishment's tracking system. We have revised § 1271.290 to clarify that a ''system'' involves the tracking of an HCT/P from the donor to the consignee or from the consignee to the donor; and that a ''method'' is an action that enables tracking.

(Comment 125) One comment on proposed § 1271.290(b) asserted that a single designated establishment should collect tracking information and maintain the entire history of collection, processing, and release. Another comment argued that tracking responsibilities should be placed on the entity that makes the product available for distribution, and that subsequent entities (i.e., distributors) should be allowed to follow that entity's existing tracking procedures.

(Response) Section 1271.290(b) provides establishments with the flexibility to participate in the tracking system set up by another establishment, provided that the system complies with all requirements in this section. However, the responsibility lies with each establishment involved in the manufacture of an HCT/P. For example, if only the establishment that made the HCT/P available for distribution were responsible for tracking, establishments ''upstream'' would not necessarily participate. This would not enable tracking from donor to consignee because the distributor would not have the information for linking the consignee to the donor, since the establishment performing recovery would be the only entity that would know the identity of the donor.

(Comment 126) Proposed § 1271.290(c) would require establishments to ensure that each HCT/P that it manufactures is assigned and labeled with a distinct identification code that relates the HCT/P to the donor and to all records pertaining to the HCT/P. One comment on this provision asked us to clarify that a single identification code may be used for an entire lot of morselized structural tissue of the same type from the same donor, even if the lot is distributed in more than one immediate container.

(Response) We agree with this comment's interpretation of the regulation.

We have added to paragraph (c) the requirement that labeling include information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor. Although § 1271.290 does not require establishments to establish a tracking system from the recipient to the donor and from the donor to the recipient, this labeling requirement will enable such tracking to be performed. An example of a labeling statement that would comply with this requirement is: ''IMPORTANT NOTICE TO END-USER: Please record this distinct identification code in your records and in the patient's file.''

(Comment 127) One comment asked us to permit tracking from production lot rather than from donor. This method would apply to lot-processed or batch-processed products manufactured using a validated sterilization method.

(Response) We decline to modify the regulation to make the requested change. However, we would consider a request for an alternative submitted under § 1271.155. The requestor should show that the proposed alternative tracking method satisfies the purposes of the requirement in § 1271.290(e).

(Comment 128) Proposed § 1271.290(d) would require an establishment to ensure that the identifier and type of HCT/P that is implanted into a recipient be recorded in the recipient's medical records, or in other pertinent records, to enable tracking from the recipient to the donor.

One comment asserted that the manufacturer has no authority over the content of the medical record and suggested that the manufacturer provide paper documentation appropriate for the medical record and notice of the Federal regulations requiring that the

information be placed in the medical record. Another comment asserted that, because of tissue establishment's inability to mandate hospital compliance, FDA should revise proposed § 1271.290(d) to allow tracking to the production lot, or eliminate the provision altogether.

(Response) We have revised paragraph (d) to remove the requirement for ensuring that information on an HCT/P is recorded in a recipient's medical records or other pertinent records. That paragraph now requires an establishment to establish and maintain a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor.

In response to Comment 126, we discuss the new requirement in paragraph (c) for label information designed to facilitate tracking between recipient and donor.

(Comment 129) Proposed § 1271.290(e) would require establishments to document, and maintain records of, the disposition of each HCT/P, to enable tracking from the donor to the recipient or final disposition. This information must permit the prompt identification of the recipient of the HCT/P, if any.

One comment asked us to specify an acceptable timeframe for the identification of the recipient. Another comment asked whether, with regard to ''prompt'' identification, the name and hospital or social security number are sufficient information to allow identification. A third comment suggested requiring tracking, not to the recipient, but to the distributor, transplant facility, or transplanting surgeon, as appropriate. This comment asserted that neither tissue banks nor the agency has the authority to mandate hospital or physician compliance with the tissue banks request for recipient information.

(Response) FDA agrees that it cannot mandate hospital or physician compliance, and we have revised paragraph (e) to require tracking to the consignee, rather than to the recipient. However, as described in Comment 119, we note that successful tracking systems have been implemented, in which hospitals readily participate. In addition, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are required to keep records that permit tracking of any tissue from the donor or source facility to all recipients or other final disposition. (Joint Committee, 2000–2001, ''Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services,'' pp. QC 36–37.)

We decline to specify a timeframe for the identification of the consignee, because the timeframe may vary with the circumstances.

(Comment 130) One comment asked for a clarification of the term ''consignee.'' This comment asked whether a hospital that receives an HCT/P is considered the consignee, or if the surgeon who uses the HCT/P is the consignee.

(Response) Either or both parties may be the consignee, depending on the particular situation. Generally, the person and/or entity to which an HCT/P is distributed would be considered the consignee.

(Comment 131) Proposed § 1271.290(f) would require establishments, at or before the time of distribution of an HCT/P, to inform the consignee in writing of the regulatory requirements and of the tracking method that the establishment has put into place. The establishment would also be required to document that the consignee agreed to participate in its tracking method and to take all necessary steps to ensure compliance with the requirements of § 1271.290.

Several comments questioned how proposed § 1271.290(f) would work. One comment asked whether a signed agreement would have to be obtained before sending the tissue, and noted that this would be difficult. This comment also asked who should be authorized to sign the agreement. Another comment noted that it sends a ''tissue usage form'' with its tissues, but that many facilities do not return the form; this comment further noted that a contract does not always exist between a tissue bank and the end user. Several comments asserted that tissue banks lack the authority or means to ensure compliance with the regulation and should not be held responsible for gathering tracking information, and one comment asked how far an eye bank must go to demonstrate that it has attempted to obtain an agreement from the consignee. One comment stated that a tissue facility cannot and should not withhold tissue for a prior failure of a facility to provide required documentation, and that if it did so, another source of tissues would be sought.

One comment expressed concern that: (1) Establishments may develop agreements that are least burdensome rather than most effective; (2) an establishment would not be able to provide an HCT/P to a consignee in an emergency until the consignee developed a tracking system; (3) the tracking requirements conflict with the new privacy rules, because a tissue establishment must review recipient records to ascertain whether a consignee maintained an adequate system; (4) patients change practitioners or localities without providing their new addresses; and (5) it would be unwieldy and unrealistic for an establishment with thousands of consignees to take all necessary steps to ensure their compliance.

(Response) We have removed the requirement in proposed paragraph (f) to obtain agreement from a consignee to participate in an establishment's tracking system.

19. Complaint Files (§ 1271.320)

Proposed § 1271.320 would require each establishment to establish and maintain procedures for the prompt review, evaluation, and documentation of all complaints, and the investigation of complaints as appropriate. We defined ''complaint'' in proposed § 1271.3(ii) and have made several changes to that definition, now renumbered § 1271.3(aa), which are discussed at Comment 13.

We have revised § 1271.320 so that its requirements relate to the core CGTP requirements.

(Comment 132) One comment asked us to clarify the meaning of ''promptly.''

(Response) We expect complaints to be investigated quickly enough to meet the reporting requirements, in case the complaint necessitates reporting. However, because the interpretation of the term ''promptly'' is somewhat vague, we have replaced ''promptly'' in paragraph (c) with ''as soon as practical.''

(Comment 133) Two comments raised concerns about the requirement in proposed § 1271.320(b) that confidential complaint files be made available for review and copying upon request from an authorized FDA employee.

(Response) We recognize the comments' concerns about maintaining donor and patient confidentiality. When copying complaint files, the agency will take steps to protect the identity of the donor or patient in conformance with 21 CFR parts 20 and 21.

D. Part 1271, Subpart E—Additional Requirements for Establishments Described in § 1271.10

1. Applicability (§ 1271.330)

Proposed § 1271.330 explained that the regulations in subpart E would be applicable only to HCT/Ps described in § 1271.10, i.e., regulated solely under section 361 of the PHS Act and the regulations in part 1271.

We received no comments on this section. We have, however, modified

§ 1271.330 to state that the provisions in subpart E (on reporting and labeling) are currently being implemented only for nonreproductive HCT/Ps described in § 1271.10 and regulated solely under 361 of the PHS Act and the regulations in this part, and the establishments that manufacture them.

2. Reporting Requirements (§ 1271.350)

Proposed § 1271.350(a) sets out requirements for reporting adverse reactions, and § 1271.350(b) deals with reports of product deviations (now called ''HCT/P deviations'').

(Comment 134) One comment on proposed § 1271.350 stated that the section is unnecessarily burdensome because a professional organization already requires reporting, and requested ''deemed status'' for that organization.

(Response) We disagree that these reporting requirements are duplicative. Reporting to professional organizations is not required under these regulations. More importantly, we do not receive reports of adverse reactions and HCT/P deviations from professional organizations.

Adverse Reaction Reporting (§ 1271.350(a))

(Comment 135) Several comments asserted that our authority to require adverse reaction reports is limited to those that involve the transmission of communicable disease or product contamination. Three comments requested that reportable adverse reactions be defined, for corneas, as any communicable or other disease transmitted by and attributable to transplantation of donor eye tissue, including infection and biologic dysfunction, and any systemic infectious disease that develops in a recipient. One comment requested that the rule be revised to take into account that transplants can be rejected or cause reactions such as graft-versus-host disease.

(Response) You are now required to investigate any adverse reaction involving a communicable disease. You must make a report if the adverse reaction meets one of the criteria set out in § 1271.350(a)(1). We decline to set out specific requirements for corneas but note that the situations described in the comments would meet the requirements in § 1271.350(a) for reporting adverse reactions. Problems not connected with communicable disease transmission are not required to be reported e.g., primary graft failure.

(Comment 136) One comment suggested limiting reporting requirements to adverse reactions ''directly related to the product'' to reflect that an HCT/P establishment is not responsible for reporting communicable disease transmission from other sources (e.g., blood products administered during surgery).

(Response) We decline to make the suggested change. It may take longer than 15 days for an establishment to determine whether or not an adverse reaction is directly related to an HCT/P. For the protection of the public health, it is more important for information about the transmission of a communicable disease or HCT/P contamination to be reported to us within 15 days, even if further followup indicates that communicable disease transmission came from a source other than the HCT/P.

However, we note that in cases where there is no reasonable possibility of a relationship between an unintended and noxious response and the HCT/P, then the event would not be considered an adverse reaction under § 1271.3(y), and reporting would not be required under § 1271.350(a).

(Comment 137) One comment asked whether, if the investigation of a complaint points to a cause other than a failure of an eye bank's good tissue practice, the eye bank is required to report these results.

(Response) If immediate investigation indicates that there is not a reasonable possibility of a relationship between an unintended and noxious response and the HCT/P, then the event is not considered an adverse reaction and you are not required to report it. If, however, there exists a reasonable possibility that the HCT/P caused the event, then the event is an adverse reaction and it may be reportable under § 1271.350(a). If, after you have made a required report, you discover additional information, you must report this information to the agency under § 1271.350(a)(3) within 15 calendar days of receipt of the new information. If your investigation determines that the HCT/P did not cause the unintended and noxious response, then you must submit this information to FDA.

(Comment 138) Proposed § 1271.350(a) would require you to make reports of adverse reactions to us within 15 calendar days of the initial receipt of the information. Several comments suggested extending this timeframe to 30 days to allow for more thorough follow-up; one comment suggested 30 to 60 days; and another comment suggested 30 days, in the absence of death or disease transmission.

(Response) We disagree with these comments. The timeframe set out in § CFR 1271.350(a) is consistent with adverse reaction reporting requirements for other regulated products (see 21 CFR 314.80 and 600.80; Medical Device Reporting is required within 10 days (21 CFR 803.10)). The adverse reactions that must be reported to the agency under § 1271.350(a) warrant action in less than 1 or 2 months. It is reasonable for us to require reporting without delay of an adverse reaction that is fatal or life-threatening, results in permanent impairment of a body function or permanent damage to body structure, or necessitates medical or surgical intervention, including hospitalization. We recognize that followup may be appropriate, and § 1271.350(a)(3) sets out procedures for submitting new information to the agency or responding to an agency request for additional information.

(Comment 139) Several comments objected to the breadth of the proposed requirement for reporting cases where medical or surgical intervention is required. Two comments suggested adding the phrase ''to preclude permanent impairment of a body function or permanent damage to a body structure'' for consistency with medical device reporting regulations (see § 803.3(bb)).

(Response) We decline to make the suggested change because the communicable disease risks with HCT/Ps are different from the types of risks associated with most medical devices. It is important for FDA to know of infections that may have been caused by HCT/Ps even if permanent impairment of a body function or permanent damage to a body structure is not likely, because such infections may alert us to broader issues (e.g., a positive donor who was the source of additional HCT/Ps; CGTP failures in the establishment). For this reason, we would generally consider that an infection at the site of a transplant would be reportable under § 1271.350(a).

(Comment 140) One comment stated that it is unclear which establishment must report adverse reactions to FDA.

(Response) Any establishment that receives information (e.g., through a complaint) about an adverse reaction related to an HCT/P that it made available for distribution must comply with § 1271.350(a). We have inserted this language into § 1271.350(a) for clarity.

(Comment 141) One comment noted that it may be important to specify the need to facilitate, encourage, and even solicit adverse reaction information by establishments themselves. The comment further noted that the probability of receiving this information may be determined in part by the

presence or absence of a well-defined active followup program implemented by the establishment.

(Response) We agree with this comment and encourage establishments to develop programs to help them comply with the reporting requirements in § 1271.350.

HCT/P Deviation Reporting (§ 1271.350(b))

(Comment 142) One comment on proposed § 1271.350(b) asserted that the regulation should not require reporting of minor or unimportant deviations. Two comments criticized the proposed reporting requirement as burdensome and questioned the agency's capacity to review submitted reports. These comments suggested limiting reports to instances involving issues of disease transmission.

(Response) We have modified the proposed definition of HCT/P deviation. An HCT/P deviation as defined in § 1271.3(dd) is limited to an event that represents a deviation from applicable regulations or established specifications that may relate to the prevention of communicable disease transmission or HCT/P contamination; or that is an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease or may lead to HCT/P contamination.

(Comment 143) Two comments asked for clarification of whether deviations must be reported if the HCT/P is not distributed.

(Response) As in the proposed rule, reporting of HCT/P deviations is required only when the involved HCT/P has been distributed.

We have also clarified that the establishment must investigate all HCT/P deviations related to a distributed HCT/P for which the establishment performed a manufacturing step.

(Comment 144) One comment suggested changing the requirement to report ''as soon as possible'' to a maximum reporting period of 45 days.

(Response) We agree with this comment and have made the suggested change. In this regard, we wish to emphasize that HCT/P establishments should not wait to report deviations until after completing their corrective actions. Rather, HCT/P establishments should submit deviation reports as soon as possible but no later than 45 days after the date that the establishment first discovers information reasonably suggesting a reportable event has occurred. The reports should include information on the intended followup to be taken if followup is not completed prior to submission of the report.

(Comment 145) One comment pointed out discrepancies between proposed § 1271.350(b) and the biologic product deviations final rule, and suggested that reporting requirements be harmonized.

(Response) We have largely harmonized § 1271.350(b) with § 600.14(b), as suggested by the comment. In addition, we have clarified in § 1271.350(b)(2) your obligation to report an HCT/P deviation relating to the core CGTP requirements, if the HCT/P deviation occurs in your facility or in a facility that performs a manufacturing step for you under contract, agreement, or other arrangement. The establishment responsible for reporting HCT/P deviations relating to the core CGTP requirements would receive the necessary information from a contract establishment in accordance with § 1271.160(b)(2).

3. Labeling (§ 1271.370)

Proposed § 1271.370 would have required clear and accurate labels for each HCT/P.

Proposed § 1271.370 would apply only to 361 HCT/Ps; HCT/Ps regulated as drugs, devices, and/or biological products are subject to labeling requirements currently in place. The regulations under 21 CFR parts 201 and 610 will apply to HCT/Ps regulated as drugs and/or biological products, as will relevant statutory provisions and any conditions of product licensure or approval. HCT/Ps regulated as devices are subject to the labeling requirements in 21 CFR part 801, in addition to the provisions of the act and any applicable conditions of approval or clearance. In the proposed rule, we proposed to interpret several current regulations as encompassing the information set out in proposed § 1271.370(a), and stated that we would expect the information listed in that section to appear on the label or package insert of those products regulated as biological drugs or devices (66 FR 1508 at 1522). We received no comments on this proposal.

To coordinate with the requirement in § 1271.290(c) that you label each HCT/P with a distinct identification code, we have added to § 1271.370 the requirement that this code be affixed to the HCT/P container.

(Comment 146) One comment stated that the required label information would not fit on vials and requested that this information be permitted on labeling. Another comment asserted that putting the name and address of the establishment that determined donor eligibility on the label would breach donor/recipient confidentiality and suggested that this information appear instead in the package insert.

(Response) The establishment name and address information is important to enable traceability if needed. However, we recognize the difficulty in fitting this information on the HCT/P label, and we have changed the regulation in § 1271.370(c) to require that this information must either appear on the HCT/P label or accompany the HCT/P. We also note that when we use the term ''label'' in this subpart, we mean either: (1) Affix to the HCT/P container, or (2) attach a tie-tag with the appropriate information to the container.

(Comment 147) Proposed § 1271.370(a)(3)(ii) would require warnings on the label or package insert, where appropriate. One comment stated that guidance is needed on ''warnings.''

(Response) In §§ 1271.60, 1271.65, and 1271.90 of the donor-eligibility final rule, we now require warning statements related to informing the recipient about certain unusual circumstances, e.g., ''WARNING: Advise patient of communicable disease risk'' when an HCT/P is distributed before completion of the donor eligibility determination. These warning statements must appear on the HCT/P label. In addition, the establishment should determine what other information the user needs to know before using an HCT/P; this information would be considered ''other warnings'' (we have revised § 1271.370(c)(3)). Other warnings would include information about risks resulting from procedures to reduce communicable disease risks during the manufacture of an HCT/P. An example would be a warning that the product was processed aseptically and is not sterile (e.g., may harbor microorganisms).

Because certain warnings are required to appear on the label itself, we have added § 1271.370(b)(4), which lists, as information that must appear on the label, warnings required under § 1271.60, § 1271,65, or § 1271.90, if applicable.

(Comment 148) One comment stated that some of the labeling provisions exceed the statutory authority because the relationship to communicable disease transmission is too attenuated.

(Response) We have revised § 1271.370 to strengthen the connection between the labeling requirements and the prevention of communicable disease. For example, § 1271.370(c)(4) now requires instructions for use when related to the prevention of the introduction, transmission, or spread of communicable diseases. Other information we have required to be included in the labeling is intended to facilitate proper use and tracking of the HCT/P; both are essential to prevent the

spread of communicable disease. We have removed proposed paragraph (b); § 1271.370 no longer covers claims.

(Comment 149) One comment on proposed § 1271.370(b) asserted that HCT/Ps with claims for reconstruction or repair should be regulated under section 351 of the PHS Act because it cannot be assumed, in the absence of substantial clinical evidence, that these products perform as intended. The comment provided as an example autologous expanded cartilage.

(Response) As previously noted, we have removed the proposed provision on claims from § 1271.370. However, the comment's scope extends beyond the proposed language, and for that reason we note our disagreement. HCT/Ps with claims for ''reconstruction or repair'' can be appropriately regulated solely under section 361 of the PHS Act if such HCT/Ps meet all of the criteria in § 1271.10, including minimal manipulation and homologous use. To further clarify this point, we have added the terms ''repair'' and ''reconstruction'' to the definition of ''homologous use'' under § 1271.3(c).

The example provided by the comment is not appropriate. Autologous expanded cartilage cells are not regulated solely under section 361 because they are more than minimally manipulated when they are cultured and, thus, do not meet the criteria in § 1271.10.

(Comment 150) Two comments asserted that proposed § 1271.370(b)(2) is unnecessary and could create confusion regarding the definition of homologous use. These comments suggested removing the paragraph in question and allowing the existing definition of ''homologous use'' to stand as the sole definition.

(Response) We agree with this comment and have removed the proposed paragraph on claims from § 1271.370. ''Homologous use'' is defined in § 1271.3(c)(the registration final rule) as ''the replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.'' As previously noted, we have added reconstruction and repair to the definition of ''homologous use'' under § 1271.3(c).

(Comment 151) One comment asserted that we should clarify this rule to identify examples of homologous use claims.

(Response) This rule no longer contains language relating to homologous use claims. However, we take this opportunity to note that the examples of homologous and nonhomologous claims given in the registration final rule are still valid, with one exception (see 66 FR 5447 at 5458). After reviewing additional data from one manufacturer, we now consider the use of that manufacturer's minimally manipulated amniotic membrane alone for ocular repair as homologous. However, when amniotic membrane is combined with limbal stem cells, such an HCT/P is regulated under section 351 of the PHS Act.

E. Part 1271, Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10

1. Applicability (§ 1271.390)

Proposed subpart F of part 1271 contains provisions on inspections; HCT/Ps offered for import; and orders of retention, recall, destruction, and cessation of manufacturing. Subpart F would apply only to those establishments described in § 1271.10 (i.e., those establishments that manufacture HCT/Ps regulated solely under the authority of section 361 of the PHS Act and the regulations in part 1271, and not as drugs, devices, and/or biological products). We received no comments on this section.

2. Inspections (§ 1271.400)

Proposed § 1271.400 would require an establishment to permit an authorized representative of FDA at any reasonable time and in a reasonable manner to inspect the establishment.

(Comment 152) In the proposed rule, we invited comments on possible alternative inspection and enforcement provisions that would leverage our resources, be cost-effective, and achieve the public health goals of the proposed rule (66 FR 1508 at 1523). We received four comments in response to this request. These comments suggested third-party inspections, training of FDA representatives by professional organizations, and special recognition for accreditation.

(Response) We appreciate these helpful comments. Instituting a third-party inspectional process would require additional resources (for startup) and would also require that establishments have an inspectional history. Because many HCT/P establishments do not have an inspectional history, and because of resource limitations, we decline to adopt this approach at present. However, we intend to reconsider the idea in the future.

The suggestion that the agency and industry organizations partner to train FDA representatives is also a good idea, and would represent the continuation of existing FDA practice. To date, both EBAA and AATB have participated in regional training courses for FDA representatives, and we hope to continue this useful practice.

The suggestion that special recognition be given to establishments that are accredited by a professional association has already been implemented, in that we give establishments that are not accredited a higher priority for inspection.

(Comment 153) One comment suggested amending § 1271.400 to require that FDA representatives be appropriately trained to examine establishments that manufacture HCT/Ps according to the type of tissue manufactured by the facility.

(Response) We decline to modify § 1271.400 as suggested. FDA representatives receive significant training on an ongoing basis, and they will continue to do so.

(Comment 154) One comment expressed concern that inspections would disrupt the practice of reproductive medicine.

(Response) FDA inspections involve document review; interviewing employees; and physical inspection of equipment, products, labeling, facilities, and operations. We conduct these activities in a manner that is as unobtrusive as possible, and our expectation is that an establishment will be able to conduct business as usual during the course of an inspection. FDA has extensive experience conducting inspections in a variety of clinical settings (e.g., hospital bloodbanks performing time-critical activities and confidential donor screening).

We recognize and understand that responsible personnel at times may be involved in procedures that make them temporarily unavailable to the FDA representative. In this situation, the FDA representative will perform some other aspect of the inspection that does not require the responsible person's presence until that person is again available to be interviewed.

Inspections will focus on assessing compliance with applicable requirements; to make this clear, we have added the word ''applicable'' to the first sentence of § 1271.400(a). For example, the inspection of an establishment that engages solely in processing would address processing-related requirements, rather than donor testing and screening. With respect to establishments that manufacture reproductive HCT/Ps regulated solely under section 361 of the PHS Act and these regulations, an inspection would be limited to issues of compliance with the donor-eligibility requirements

contained in subpart C of this part, but would not consider compliance with the requirements in subparts D and E.

(Comment 155) One comment stated that it is not appropriate for the interpretation of SOPs and the validation of tissue banks to be subject to the individual regulatory representative's judgment and that a more standard approach is needed.

(Response) We agree with the concerns expressed by this comment, and note that for several years FDA has used a standard approach for tissue establishment inspections. Compliance Program 7341.002 (Inspection of Tissue Establishments) provides standard inspectional, regulatory, and administrative guidance to all FDA representatives involved in conducting inspections of human tissue establishments and to management personnel who evaluate the results of those inspections. FDA representatives evaluate the adequacy of a firm's SOPs and process validation or verification on site. All observations they may record on a Form FDA–483 are subject to further review by FDA management, to ensure consistency with FDA regulations, before any regulatory action is taken. The firm can respond to items recorded on the Form FDA–483 during the discussion with the FDA representative at the conclusion of the inspection or subsequently in writing, if the firm wishes to do so.

(Comment 156) Two comments on proposed § 1271.400(a) requested that we provide from 1 to 5 days notice before an inspection.

(Response) FDA has tried a variety of announced and unannounced inspection procedures in the past. Our current practice is generally not to preannounce inspections because such a commitment affects the overall productivity of field staff. An establishment must be in compliance at all times, which should make it unnecessary to preannounce an inspection for the establishment to ''prepare'' for an inspection. For clarity, we have modified the language of the final regulation to state that an inspection may be made with or without ''prior notification.''

(Comment 157) Proposed § 1271.400(c) states that FDA's representative will call upon the most responsible person available at the time of an inspection. Three comments requested that this representative be the executive director or a person functioning in that position at the time of the inspection. One comment pointed out that eye banks are usually small and that key staff may be out of the bank performing other duties.

(Response) We decline to modify the regulation as requested. Firms should have a plan in place to instruct their staff exactly who would accompany an FDA representative in the absence of the most responsible person. The FDA representative will determine whether or not a meaningful inspection can be conducted, given the available personnel.

(Comment 158) Proposed § 1271.400(c) also states that the FDA representative conducting an inspection may question the personnel of the establishment, as the representative deems necessary. One comment objected to the exercise of our discretion, if unfettered, to question any employee and stated that, historically, FDA has allowed companies to designate spokespeople. Another comment asserted that FDA should question a senior official who is well acquainted with the SOPs of the facility (not just the most responsible person available).

(Response) It is agency practice for the FDA representative conducting an inspection to observe and interview employees to determine if they are performing their various functions in accordance with the firm's current SOPs, to determine if activities are being documented concurrently with the performance of each significant step, and to evaluate if employees are properly trained and supervised. We agree that it is a good idea to make a spokesperson available to accompany the FDA representative and provide historical, statistical, and administrative information about the company. All employees at an establishment should be well acquainted with the SOPs related to their work in that establishment.

(Comment 159) Under proposed § 1271.400(d), FDA's representative may review and copy any records required to be kept under part 1271 and may take photographs or make videotapes. One comment questioned FDA's intentions with respect to records of quality assurance activities. Another comment asked that this section be revised to exempt from FDA review records of management review, quality audits, supplier evaluations, and other types of information (e.g., financial). One comment suggested new language limiting reproduction to data that would relate to possible communicable disease transmission and/or biologic dysfunction of tissue.

(Response) The FDA representative may review and copy any records required to be kept under part 1271. Financial records and personnel records are not required records under part 1271. Given the scope of the requirements in part 1271 and their focus on preventing the introduction, transmission, or spread of communicable disease, it is unnecessary to limit § 1271.400 as suggested. With respect to quality audits, while some firms choose to provide quality audits to FDA, FDA's current practice is generally not to request or copy the actual quality audit reports except in certain limited circumstances (FDA Compliance Policy Guide 130.300). However, the firm should have a mechanism to demonstrate to the FDA representative that quality audits are being performed and that corrective actions are being implemented when problems have been identified.

(Comment 160) Several comments questioned the provisions of proposed § 1271.400(d) on photography and videos. Two comments questioned the agency's authority to do so.

(Response) FDA's practice is to record images (e.g., by way of photographs or videotapes) to accurately record the conditions in an establishment. These tools may be employed as long as the inspection is lawful. See *United States* v. *Gel Spice Co.*, 601 F. Supp. 1214, 1220 (E.D.N.Y. 1985); *United States* v. *Acri Wholesale Grocery Co.*, 409 F. Supp. 529, 532–533 (S.D. Iowa 1976). Inspections conducted under regulations issued under section 361 of the PHS Act are lawful. However, we have modified the wording of § 1271.400(d) to delete the specific references to photographs and videotapes, and to state instead that FDA's representatives may use other appropriate means to record evidence of observations during inspections conducted under this subpart.

FDA also has the authority to take samples to support observational findings. To clarify this previously implied capability, we have added to § 1271.400(d) that FDA also may take samples.

4. Imports (§ 1271.420)

When an HCT/P is offered for entry, proposed § 1271.420 would require the importer of record to notify the director of the district of the FDA having jurisdiction over the port of entry. The HCT/P would be held intact until it is released by FDA.

We have made several revisions to § 1271.420(a) and (b) for clarity and for consistency with agency import policy. We have replaced the phrase ''offered for entry'' with the more accurate phrase, ''imported or offered for import.'' Consistent with other agency regulations, HCT/Ps ''imported or offered for import'' include, not only

those HCT/Ps imported or offered for import into the United States for use, storage, or distribution in the United States, but also those imported or offered for import for transshipment through the United States to another country, for future export, or for use in a United States Foreign Trade Zone. (See, e.g., ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' interim final rule, 68 FR 58974 at 58990 and 58991, October 10, 2003.)

We have specified in paragraph (a) that notification of the director of the FDA district having jurisdiction over the port of entry may occur either before or at the time of importation. The term ''port of entry'' is defined in 19 CFR 101.1 as any place designated by Executive order of the President, by order of the Secretary of the Treasury, or by act of Congress, at which a Customs officer is authorized to accept entries of merchandise, to collect duties, and to enforce the various provisions of the Customs and navigation laws. To make certain that importers understand our expectations (e.g., accompanying records required under § 1271.55, and entry information required by United States Bureau of Customs and Border Protection), we have added the requirement that the importer of record must provide sufficient information for FDA to make an admissibility decision.

Finally, we have replaced the phrase in proposed paragraph (b), ''until it is released by FDA,'' with ''until an admissibility decision is made,'' which more accurately reflects FDA's actions.

(Comment 161) One comment suggested the addition of language to clarify that the regulation only applies to HCT/Ps ''intended for clinical use.''

(Response) We agree that § 1271.420 applies only to HCT/Ps intended for clinical use, but we do not consider it necessary to modify the regulation as suggested. The regulations in part 1271 do not apply to establishments that use HCT/Ps solely for nonclinical scientific or educational purposes (§ 1271.15(a)); moreover, § 1271.3(d) defines an HCT/P as intended for implantation, transplantation, infusion, or transfer into another human (i.e., clinical use).

(Comment 162) One comment requested an exemption for reproductive HCT/Ps imported under the authority of the owner of the reproductive materials.

(Response) We have modified § 1271.420 to except from its provisions reproductive HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in this part, and donated by a sexually intimate partner of the recipient for reproductive use. (See § 1271.420(c).)

(Comment 163) One comment asked about the relationship between the proposed FDA inspection and inspections of hematopoietic stem/progenitor cells currently performed by other agencies, such as the Department of Transportation (DOT).

(Response) The inspection that FDA will conduct with respect to imported HCT/Ps is distinct from inspections conducted by other agencies. For example, DOT inspects for compliance with its labeling and packaging regulations, whereas FDA inspects for compliance with the regulations that require accompanying documentation and labeling information about donor screening and testing.

(Comment 164) Proposed § 1271.420(b) would require that an HCT/P offered for import must be held intact until it is released by FDA. Four comments on this provision raised strong objections to this provision because of its potential adverse effect on imported hematopoietic stem/progenitor cells. These comments asserted that any delay is life-threatening and that these HCT/Ps should be immediately cleared through customs.

(Response) Prior to infusion, recipients of peripheral blood stem/progenitor cells undergo a myeloablative treatment regimen (i.e., high dose chemotherapy and total body irradiation), which may have begun before importation takes place. We agree with the comments' concerns about the risk of delay in this situation and have accordingly revised § 1271.420. Section 1271.420(d) states that this section does not apply to peripheral blood stem/progenitor cells regulated solely under section 361 of the PHS Act and the regulations in this part, except that paragraphs (a) and (b) apply when circumstances occur under which such imported peripheral blood stem/progenitor cells may present an unreasonable risk of communicable disease transmission, which indicates the need to review the information referenced in paragraph (a). We believe this provision affords access to peripheral blood stem/progenitor cells and appropriate public health protection. We also believe that situations in which information would be needed for review under paragraph (a) will be rare or unlikely to occur. Because the regulations in subpart F apply only to those HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in part 1271, the exception in paragraph (d) affects only the subset of peripheral blood stem/progenitor cells that are regulated in this way (e.g., those for autologous use, or allogeneic use in a first-degree or second-degree blood relative). In the event that issues arise with respect to imports of peripheral blood stem/progenitor cells that are regulated as biological drugs, and so are subject to the import provisions in section 801 of the act (21 U.S.C 381), we would consider those issues and take appropriate actions.

Consideration of these comments has led us to make a clarification to § 1271.420(b) that will apply to HCT/Ps that are not excepted from these import provisions. Paragraph (b) states that an HCT/P offered for import must be held intact by the importer or the consignee, under conditions necessary to prevent transmission of communicable disease, until an admissibility decision is made by FDA. Under paragraph (b), the HCT/P may be transported under quarantine to the consignee, while FDA reviews the documentation accompanying the HCT/P. While the HCT/P is being held intact pending an admissibility determination, under conditions that prevent the transmission of communicable disease, the HCT/P cannot be manipulated in any way or administered. If the FDA district office determines that the entry is in compliance with the appropriate FDA regulations, the district office will notify the importer of record. Under paragraph (a), the importer can facilitate the entry process by notifying the FDA district office before the actual import occurs.

3. Orders of Retention, Recall, Destruction, and Cessation of Manufacturing (§ 1271.440)

Proposed § 1271.440 describes the procedures FDA would use to issue orders for the retention, recall, and destruction of HCT/Ps and for the cessation of manufacturing operations. Under the proposed rule, we would issue such orders upon an agency finding that an HCT/P or establishment is in violation of the regulations in subparts C and D.

(Comment 165) Several comments asserted that these enforcement actions are too dramatic and far-reaching. One comment argued that the standard for taking these actions should be higher than mere CGTP deficiencies and should involve imminent danger to public health. One comment asserted that the regulation should define procedures to be followed to protect the rights of the manufacturer to due process.

(Response) We disagree with the view that the proposed enforcement procedures for noncompliance with CGTP regulations are too dramatic and

far-reaching. However, to address the concerns raised in these comments, FDA has revised the proposed procedures for serving upon an establishment an order to cease manufacturing. We have clarified that an order to cease manufacturing will be effective immediately only when the agency finds that there are reasonable grounds to believe that there is a danger to health. In other circumstances, the order will be effective after one of the following events, whichever is later:

- Passage of 5 working days from the establishment's receipt of the order; or
- If the establishment requests a hearing in accordance with paragraph (e) and part 16 (21 CFR part 16), a decision in, and in accordance with, those proceedings.

FDA reiterates that, as stated in § 1271.440(e), part 16 provides an opportunity to request a hearing concerning any matter related to orders of retention, recall, destruction, and cessation of manufacturing of HCT/Ps (§ 16.1(b)(2)). Part 16 permits FDA to

> * * * take such action pending a hearing * * * as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis. (Emphasis added). (§ 16.24(d))

If FDA issues an order to cease one or more steps in the manufacture of an HCT/P, or issues an immediately effective order to retain, recall, and/or destroy the HCT/P, and the Commissioner of Food and Drugs (the Commissioner) does not stay the order upon receiving a hearing request, FDA will provide an opportunity for an expedited hearing. (See § 1271.440(e).) As a technical amendment, we are revising § 16.1(b)(2) by adding § 1271.440(e).

(Comment 166) One comment stated that these enforcement actions should relate to a violation that may result in communicable disease transmission.

(Response) We agree. This final rule, issued under the authority of section 361 of the PHS Act, is intended to help prevent the introduction, transmission, or spread of communicable disease. In response to this comment, we have revised paragraph (a) to state that a violative HCT/P includes an HCT/P that is infected or contaminated so as to be a source of dangerous infection to humans. We have also revised that paragraph in two other ways. Rather than simply referring to an HCT/P or an establishment ''in violation of the regulations of this part,'' the regulation now refers to

> * * * reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of the regulations in this part and, therefore, the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission * * * or an establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission.

(Comment 167) One comment asked for clarification of the term ''recall'' and suggested that ''notification'' might be a more appropriate term in cases where the tissue has already been transplanted.

(Response) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by FDA (§ 7.40(a)) (21 CFR 7.40(a)). Public notification is an important part of a recall strategy (see 21 CFR 7.50), especially where physical recall may be impossible or impractical. Guidelines on voluntary recalls, including public notification, are set out in §§ 7.40 through 7.59 (21 CFR 7.40 through 7.59). To the extent applicable, FDA follows the same policy regarding notifications for mandatory recalls. The term ''recall'' encompasses all elements of a recall strategy, including notification, and no change to the rule is necessary.

(Comment 168) One comment noted that issuance of a recall or destruction order creates a potential for raising public alarm, and suggested the addition of a new paragraph requiring FDA to conduct a followup investigation to determine the reasonableness and necessity of its initial findings.

(Response) Concerns about raising public alarm upon issuance of an order of recall or destruction are no greater than those associated with ordered recalls of other regulated products. FDA does not intend to pursue minor violations of part 1271, but would take regulatory action in urgent situations to protect public health.

(Comment 169) One comment requested that FDA acknowledge the limitations on corrective actions arising from the ownership status of reproductive HCT/Ps.

(Response) We acknowledge the difficulty of the issues raised by the comment, and we note that the provisions of § 1271.440 provide the agency with a range of enforcement options. For example, in some instances a firm working with FDA could develop a recall strategy that involved notification of affected parties. We have added paragraph (f) to § 1271.440, which states that FDA will neither issue an order for the destruction of reproductive tissue, nor will it carry out such destruction itself.

(Comment 170) One comment asserted that the order to cease manufacturing under proposed § 1271.440 violates the Due Process Clause of the Fifth Amendment of the United States Constitution. Citing *Bell* v. *Burson*, 402 U.S. 535, 542 (1971), the comment stated that, under the Due Process Clause, before a State seeks to terminate an entitlement (e.g., pursuit of a profession), it must provide notice and opportunity for hearing appropriate to the nature of the case before the termination becomes effective, ''except in emergency situations.'' The comment noted that although proposed § 1271.440 permits a facility to request a hearing, it does not provide a date on which a hearing must be held or that a hearing must be held at all. This provision also does not specify when a decision regarding the validity of the order is to be made. The comment also observed that an order under proposed § 1271.440 could be of potentially infinite duration, lasting as long as the agency believes that regulatory compliance has not been achieved. Another comment also asserted that, under *American Bus Ass'n* v. *Slater*, 231 F.3d 1 (D.C. Cir. 2000), this provision exceeds FDA's statutory authority under section 361 of the PHS Act and is invalid.

(Response) We disagree that § 1271.440 is either unconstitutional or outside the agency's statutory authority. Under section 361 of the PHS Act, FDA is expressly authorized to enforce the regulations it issues to prevent the introduction, transmission, or spread of communicable disease through such means as inspection, disinfection, sanitation, destruction, and ''other measures as in [FDA's] judgment may be necessary.'' Orders to retain, recall, destroy, or cease manufacturing are such other measures that we have concluded are necessary to prevent communicable disease transmission. An order to cease manufacturing does not terminate any interest or right related to the pursuit of a profession. Such an order is intended for use in situations when needed to prevent the spread of communicable disease and is lawful so long as we provide an opportunity for a hearing ''at a meaningful time and in a meaningful manner''; the hearing does not need to be provided before the order issues. *Armstrong* v. *Manzo*, 380 U.S. 545, 552 (1965). To clarify this intent we have added language to § 1271.440(a)(3) stating that an order to cease manufacturing until compliance with the regulations in part 1271 has been achieved will have immediate effect

only when FDA determines that there are reasonable grounds to believe that there is a danger to health if the establishment continues to manufacture (see Comment 165 of this document).

Under § 1271.440 of this final rule, any person who receives an order to cease manufacture will have the opportunity to request an expedited hearing in accordance with part 16. We have also included a statement in § 1271.440(e) that FDA will provide an opportunity for an expedited hearing on an order of cessation that is not stayed by the Commissioner, when a request for a hearing is made in accordance with part 16. We decline to provide a specific timeframe within which a hearing must be held or within which a final decision must be rendered. Each request for a hearing should be reviewed within the timeframe appropriate for its specific circumstances. Some cases may need resolution within a few days, while other, more complicated cases may need more time to prepare for a hearing or to resolve the issues.

The comment's reliance on *American Bus Ass'n* v. *Slater* is misplaced. In *American Bus*, the United States Court of Appeals for the District of Columbia invalidated a Federal regulation that imposed money penalties (a fine), which was not expressly authorized under the Americans with Disabilities Act (ADA). The ADA explicitly provided for injunctive or similar preventive relief and permitted civil proceedings for money damages, but was silent about the imposition of money penalties. The Court held that ''Congress unambiguously intended to preclude [the Department of Transportation] from authorizing money damages.'' (231 F.3d at 4.) By contrast, section 361 of the PHS Act expressly authorizes FDA to enforce regulations using such means as

* * * inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in [FDA's] judgment may be necessary.

Like an order of fumigation, disinfection, and sanitation, an order to cease manufacturing is a remedial action taken to put important protections in place to prevent communicable disease transmission. Unlike the fine in *American Bus*, it is not a punitive action.

As explained in the proposed rule and earlier in this response, it is FDA's judgment that an order to cease manufacture of an HCT/P may be necessary to prevent the introduction, transmission, or spread of communicable diseases. Such an order would be issued where violations created an urgent situation involving a communicable disease, because an establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission (e.g., an establishment fails to test donors in compliance with subpart C of part 1271). By contrast, we would not issue an order to cease manufacture to punish an establishment for past violations or violations that do not result in an urgent situation.

(Comment 171) One comment asserted that the 5-day timeframe for recall or destruction in proposed § 1271.440(c) is inadequate.

(Response) FDA disagrees that 5 days is an insufficient timeframe. However, we recognize that circumstances may exist or occur that would require a time period other than the prescribed 5 working days for the implementation of corrective action or recall and/or destruction of HCT/Ps. Accordingly, we note that § 1271.440(c)(1), which states that ''[a] written order issued under paragraph (a)(1) of this section will ordinarily provide that the HCT/P be recalled and/or destroyed within 5 working days from the date of receipt of the order'' (emphasis added), provides for circumstances where we determine that an alternate timeframe is appropriate. The response to comment 167 describes the recall guidelines. In the event that FDA issues an order of destruction for HCT/Ps, such destruction would occur in accordance with applicable local, State, and Federal laws (i.e., Environmental Protection Agency) and under FDA supervision.

F. Economic Impacts

(Comment 172) Three comments suggested that the CGTP rule would impose significant cost burdens on affected entities and that FDA has significantly underestimated the compliance costs.

(Response) We disagree. Our analysis of economic impacts suggests that the cost burden of the CGTP final rule will not be significant. Further, these comments did not provide any data that refute FDA's cost estimates or suggest alternative estimates of compliance costs.

(Comment 173) Three comments provided alternative estimates of the financial impact/compliance costs of the CGTP rule for eye banks ranging from $41,533 to $180,000 per year. One of these comments suggested that the financial impact of the CGTP rule could force many eye banks out of business.

(Response) FDA is unable to assess these comments as no information or data were provided to support the estimates of financial impact/compliance costs. The agency does not anticipate a significant economic impact on the eye bank industry because nearly all eye banks are believed to be following the current EBAA standards, which meet or exceed most requirements of the CGTP rule. We therefore disagree that the impact of the rule could force many eye banks out of business.

(Comment 174) One comment stated that most of the requirements of the CGTP rule are not difficult to meet but will require additional steps and documentation. The comment also suggested that all eye banks will have to increase quality control efforts and hire a separate quality control employee to track each provision of the program which will be time consuming and expensive.

(Response) FDA realizes that the CGTP rule will impose some additional financial burden on affected entities. However, eye bank personnel who oversee the quality assurance program currently required under EBAA standards perform duties similar to those required under the CGTP final rule. Therefore, the agency does not believe that a separate quality control employee will be required. Further, FDA's analysis of economic impacts suggests that these requirements will not be overly time consuming or expensive.

(Comment 175) One comment indicated that all eye banks would have to add or revise a procedure to handle complaints and that FDA's estimate of two complaints per year is too low, especially for large volume eye banks.

(Response) The agency recognizes that some eye banks may experience a greater number of complaints. However, this estimate is designed to be representative of the number of complaints handled annually by a typical entity. The comment did not provide an alternative estimate of the number of complaints reported annually.

(Comment 176) One comment suggested that FDA (implicitly) assumed that all primary graft failures will be prevented under the rule, and provided no evidence to support any reduction in re-transplants required. Two comments suggested that FDA misinterpreted the results of a study of eye banks by Wilhelmus, et al. (1995), and failed to acknowledge the author's conclusion that no clearly defined factor accounted for most cases of primary graft failure. Two comments suggested that FDA has

overstated both the risk of primary corneal graft failure and the benefits of the rule, and that it is unlikely that CGTPs will have a significant impact.

(Response) The analysis of economic impacts has been revised to eliminate the implicit assumption that all cases of primary corneal graft failure will be prevented by the CGTP rule. The evidence on the risk, incidence and causes of primary graft failure is limited, and mostly mixed and inconclusive. While no clearly defined factor accounts for most cases of primary corneal graft failure, storage conditions (i.e. preservation media and duration) are identified in a number of studies as a possible explanatory factor, and are regulated under the CGTP final rule. The possibility that implementation of CGTPs may reduce the risk of primary corneal graft failure and generate public health benefits cannot be ruled out.

(Comment 177) One comment noted that a study reported in the journal *Cornea* (1994), found that eye bank-related factors were not important in explaining primary corneal graft failure despite the author's initial suspicions and hypothesis. Thus, FDA's cost savings estimate is greatly exaggerated.

(Response) FDA has revised its estimate of the benefits of implementing the CGTP final rule for eye banks in response to comments received, and based on additional and more recent information. However, the study cited in the comment also reports, ''interpretation of the results of this study is limited by the small sample size, which may preclude the detection of some associations,'' and, ''(m)issing data for relevant variables, most notably eye bank factors, make interpretation of related results difficult.'' (emphasis added). The comment does not provide any alternative estimates of benefits.

(Comment 178) One comment indicated that, in 1999, primary corneal graft failure occurred in only 42 cases and intraocular infection in only 14 cases out of approximately 40,000 transplants. Another comment noted that the 1994 Agency for Health Care Policy Research data referenced by FDA suggests 7,443 corneal transplants were performed that year, while the actual number reported to EBAA was 35,022.

(Response) FDA has revised the analysis of impacts of the CGTP final rule to address these comments and to incorporate the most current information available.

(Comment 179) One comment objected to the use of 1996 labor statistics to derive tissue bank employee wages.

(Response) The agency has updated the wage estimates used in the analysis of impacts of the CGTP final rule to reflect current labor costs.

(Comment 180) One comment objected to FDA's identification of the laboratory director and medical director as the same individual.

(Response) According to industry consultants, the medical director often serves as the laboratory director, particularly in small tissue facilities. Since all 134 eye banks, and a majority of facilities in the other HCT/P industry sectors, are believed to meet the criteria characterizing small entities in the relevant industry sector, FDA viewed this as an appropriate simplifying assumption.

(Comment 181) One comment noted that FDA did not add clerical expense for the revision of minor policies and procedures.

(Response) We agree that clerical expense may be incurred in the revision or preparation of a minor procedure. Therefore, FDA has added clerical expense for both the revision and preparation of a minor procedure to the cost impact estimates for the CGTP final rule.

(Comment 182) One comment objected to FDA's bundling of the cost of preparing or revising procedures with training costs.

(Response) As procedural changes generally necessitate the training or retraining of employees, the agency views such bundling as both logical and reasonable.

(Comment 183) One comment suggested that several sections of the rule lack cost estimates because no basis for predicting such costs exists.

(Response) Some requirements reviewed in the analysis of economic impacts show no costs because they are expected to impose no new financial burden on affected entities, not because there is no basis for predicting these costs. More specifically, no cost estimate is provided for a section or provision of the CGTP rule if analysis showed the requirement: (1) Does not apply, (2) has no new cost impact, or (3) is met by another subsection of the rule.

(Comment 184) One comment argued that FDA has underestimated the compliance costs for stem cell facilities, and presents alternative compliance cost figures based on FDA's analysis of economic impacts.

(Response) The compliance cost figures provided in the comment are not comparable to FDA's cost estimates for a number of reasons. First, the cost estimates provided in the comment fail to recognize and reflect an important difference between one-time costs and annual or recurring costs. Second, FDA's cost estimates are weighted based on the proportion of entities in each sector of the HCT/P industry estimated to be noncompliant with individual provisions of the CGTP rule. These noncompliance rates (weights) are based on information obtained from industry professional associations and communication with industry consultants. The cost estimates in the comment are not adjusted to reflect the estimated rates of industry noncompliance.

(Comment 185) One comment noted that the Foundation for the Accreditation of Cellular Therapy (FACT) is already inspecting to standards that are very close to the proposed regulations.

(Response) FDA does not dispute this, but following the FACT standards is voluntary, and evidence does not show that 100 percent of entities in the stem cell sector are currently following these standards. FDA believes that mandatory requirements are necessary to adequately protect public health and safety.

(Comment 186) One comment suggested that the requirement for oversight and audits would impose costs that might significantly reduce the number of participants in the National Marrow Donor Program.

(Response) We disagree. With respect to provisions governing oversight and audits, the agency notes the following. Section 1271.160(c) is expected to impose no new financial burden on affected entities. Section 1271.160(d) is expected to impose an additional burden of $228 on entities currently following FACT standards, and $1,140 in additional costs on firms not following these standards. Thus, the maximum burden on any one firm of these provisions is $1,140 per year. The agency does not view this as a significant cost burden, nor do we believe that these provisions will significantly reduce the number of donor centers participating in the National Marrow Donor Program.

(Comment 187) One comment expressed serious concerns and reservations regarding the accuracy of FDA's estimates of the risks associated with hematopoietic stem/progenitor cell transplants, and the costs and benefits of the proposed rule. Two comments argued that the costs for a bone marrow transplant are much different in 2001 than they were in 1994, and that much of the cost is for supportive care and not due to contamination of the graft. Therefore, the benefits of the rule are overstated.

(Response) FDA has revised the analysis of impacts for stem cell facilities to reflect the most recent

available risk and cost information. The agency points out that the cost for a bone marrow transplant was presented in the analysis of impacts of the proposed rule for illustrative purposes only, and was not used directly in generating an estimate of the benefits of the CGTP rule for stem cell facilities.

(Comment 188) One comment suggested that the impact of the software validation requirements on small tissue facilities would be beyond the means of many and could force them out of business. The comment suggested that § 1271.160(e) be amended to require software validation only if it is relied upon as the sole source of data for quality-related decisionmaking.

(Response) With respect to computer software validation FDA assumed: (1) None of the affected entities currently validate custom software, (2) 10 percent of all facilities in each sector have developed custom software requiring validation, and (3) validation of custom software will require 60 hours of laboratory supervisor time ($36 per hour, total cost = $2,160 per affected entity). We have modified § 1271.160(e) to indicate that either validation or verification can be performed, whichever is appropriate. Verification is less burdensome.

(Comment 189) One comment suggested that annual human heart valve allograft distribution is likely ten-fold lower (5,000–6,000) than the 61,000 annually referenced in the preamble and, further, that fewer than 10 infections per year are caused by contaminated valves since direct reports by implanting surgeons suggests less than 1 per year.

(Response) FDA has revised the analysis of impacts of the CGTP final rule to reflect both information provided in the comment and information on the risks associated with human heart valve allograft reported in the clinical literature.

(Comment 190) One comment expressed concern that the CGTP rule will be particularly onerous on small business, and would like FDA to ensure that they are not creating artificial market barriers by implementing the rule.

(Response) Nearly all facilities in the HCT/P industry are recognized as small entities and most would be similarly affected by the rule. Further, the requirements of the CGTP final rule are largely met, and in some cases exceeded, by the voluntary standards firms are required to meet to gain accreditation by professional associations in their respective HCT/P industry sectors. Finally, the agency's analysis suggests that the cost burden of the CGTP rule will not be significant (expressed as a percentage of average annual firm revenues) and, therefore, should not constitute a market barrier to small business.

(Comment 191) One comment noted that FDA chose not to certify that the rule would not have a significant economic impact on a substantial number of small entities. The comment suggested that FDA should increase its outreach to small entities in an effort to obtain the information necessary to fully assess the rule's impacts before finalization.

(Response) FDA's analysis of economic impacts is based on: Information obtained under the registration final rule; administrative data on the number of facilities within each industry sector; and the number of entities accredited by various industry associations. FDA also obtained information from individual experts identified through contact with the various industry professional associations. We explicitly recognized the uncertainty of our estimates with respect to the number of facilities in each sector, degree of compliance with current industry standards and impact of the rule on affected entities. In the proposed rule, FDA requested detailed industry comment regarding our analysis of impacts, and data sources and underlying assumptions. Finally, the agency made presentations at the annual conferences of several industry professional associations, and held individual meetings with many of these groups at their request. We believe this represents a significant level of outreach and information gathering effort.

(Comment 192) One comment suggested that, upon publication of the final rule, FDA should address all comments received regarding small business impacts and provide an assessment of small business revenues that are likely to be affected.

(Response) FDA has provided responses to all comments received in the preamble to the final rule. A comprehensive assessment of the rule's effects on small business entities is provided in the analysis of economic impacts as required under the Regulatory Flexibility Act.

(Comment 193) One comment noted that if FDA significantly underestimated firm revenues, the rule's resultant costs to firms could be far greater than those estimated.

(Response) FDA believes that if average firm revenues were significantly underestimated, then the rule's resultant costs would appear greater (as a percentage of revenues) than they really are, thereby overstating the impact of the rule. We believe the comment intended to address the effect of FDA having overestimated firm revenues. In this case, compliance costs (expressed as a percentage of revenues) would appear smaller than they really are, thereby understating the impact of the rule.

Nevertheless, FDA's estimates of average annual revenues were obtained from a variety of sources including a published study of the tissue banking industry, information obtained from industry consultants and other published data sources. In the CGTP proposed rule, FDA requested detailed industry comment on the distribution of firm revenues in the HCT/P industry, and also on our estimates of average revenue per firm. We received no detailed information in response to our request, and no comments provided alternative estimates of annual firm revenues.

(Comment 194) One comment suggested that § 1271.155 of the rule seems to allow all businesses affected by the regulation to seek an exemption or alternative from the requirements of the rule.

(Response) While an exemption from or an alternative to a particular provision of the rule may be requested by any business, the granting of such a request is by no means assured. The entity requesting an exemption or alternative must demonstrate that the exemption is justified based on scientific data and other evidence, and that the alternative satisfies the purpose of the requirement. Section 1271.155 does not provide a mechanism by which all businesses may become generally exempt from compliance with the CGTP rule.

(Comment 195) One comment assumes that § 1271.155 is FDA's attempt to comply with section 603(c) of the Regulatory Flexibility Act, which requires agencies to identify any significant alternatives available to small entities in their initial regulatory flexibility analysis.

(Response) This assumption is incorrect. The agency has written the CGTP rule broadly so as to allow comprehensive regulatory oversight of the diverse HCT/P industry. Section 1271.155 is designed to provide some flexibility, recognizing that an exemption from, or alternative to, a specific provision may be appropriate given the unique properties of a particular HCT/P.

(Comment 196) One comment noted that the FDA estimates between 75 percent and 100 percent of affected entities are already compliant with the provisions of the CGTP rule, and

questions whether the rule will create another layer of unnecessary recordkeeping and training requirements for the affected firms.

(Response) Because compliance with current voluntary industry standards is less that 100%, FDA believes the CGTP rule is the best way to establish a consistent standard of safety for marginal firms not currently following voluntary industry standards and guidelines, and to protect public health and safety. We believe that the recordkeeping and training requirements are necessary to achieve the desired public health and safety goals.

(Comment 197) One comment expressed concern that the ultimate responsibility is placed in the hands of the firm distributing the HCT/P, while other firms will also be involved in manufacturing. Noting that the distributor is responsible for maintaining documentation from all other companies involved in manufacturing the HCT/P, the comment expressed concern that this will place an unacceptable burden on small entities, and suggests that, to minimize this burden, FDA should adopt an alternative approach, discussed in the proposed rule, using a cascading set of responsibilities.

(Response) Before Comment 28, we set out a table to assist establishments in understanding their responsibilities when multiple establishment are involved in manufacturing an HCT/P. At Comments 28 through 35 we discuss the allocation of responsibilities in § 1271.150(c) and 1271.265. FDA believes that this approach is largely consistent with the cascading set of responsibilities described in the comment and discussed at Comment 31. Both approaches place responsibility on each establishment that performs manufacturing functions, with the establishment that makes the product available for distribution ultimately responsible for ensuring that the manufacturing and tracking records for an HCT/P demonstrate that it has been manufactured and tracked in compliance with the requirements of this subpart and subpart D.

IV. Effective Date of 21 CFR Part 1271 and Applicability of 21 CFR Part 1270

A. Effective Date for Part 1271

This final rule is effective May 25, 2005. All HCT/Ps recovered on or after the effective date must be in compliance with applicable requirements in part 1271.

As of the effective date, establishments that manufacture HCT/Ps defined in § 1271.3(d) that are regulated solely under the authority of section 361 of the PHS Act (as described in § 1271.10) must comply with all applicable requirements in part 1271, whether or not the HCT/P enters into interstate commerce.

The regulations under 21 CFR 207.20(f) and 807.20(d) require establishments that manufacture HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the act to register and list their HCT/Ps following the procedures in subpart B of part 1271. Section 1271.21 requires HCT/P establishments to register and list every HCT/P that the establishment manufactures within 5 days after beginning operations, or within 30 days of the effective date of the registration regulation, whichever is later. HCT/P establishments that manufacture HCT/Ps subject to investigational new drug (IND) or investigational device exemption (IDE) provisions are not required to register and list their HCT/Ps until the investigational HCT/P is approved through a Biologics License Application (BLA), a New Drug Application (NDA), or a Premarket Approval Application (PMA); or cleared through a Premarket Notification Submission (510(k)).

As required by §§ 210.1(c), 211.1(b), and 820.1(a), establishments that manufacture HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act also must comply with the requirements in subparts C and D of part 1271 in addition to all other applicable regulations.

B. Applicability of Part 1270

The retrospective application of part 1271 to human tissue, defined in § 1270.3(j), recovered before the effective date of the final rule would be overly burdensome and impractical. Therefore, we are not concurrently revoking part 1270 with the effective date of part 1271 as stated in the proposed rule (66 FR 1508 at 1524). However, we intend to revoke part 1270 in the future when we are confident that there is no human tissue regulated under 1270 available for use.

Part 1270 applies now only to human tissue defined in § 1270.3(j) and recovered before May 25, 2005. We have amended § 1270.3(j) to implement this provision. Products that meet the definition of HCT/P in § 1271.3(d) that are recovered before May 25, 2005, and that have been regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the act will continue to be subject to the applicable requirements for drugs, devices, and/or biological products.

V. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the principles identified in Executive Order 12866. The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action as defined by the Executive order and so is subject to review.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The majority of establishments within the HCT/P industry that will be affected by this final rule can be classified as small business entities, and a number of these establishments will incur new costs. Because of the limited information with which to characterize the current good tissue practice at many of these establishments, and thus the increased effort required to meet the standards of the final rule, the cost impact on small business entities is uncertain. Therefore, the following analysis, along with other relevant sections of this preamble, represents FDA's final regulatory flexibility analysis.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing

> * * any rule that includes any Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.

The current threshold after adjustment for inflation is $ 110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Based on the following economic analysis, FDA estimates that the total one-time costs to comply with this final rule will be approximately $6.91

million, and that the total annual or recurring costs will be about $7.13 million. These figures imply a total annualized cost estimate for the CGTP final rule of approximately $7.94 million to $8.11 million. The average annualized cost of CGTPs per affected small entity, expressed as a percentage of average annual revenue, ranges from 0.6 percent to 3 percent. This range of small entity impacts reflects uncertainty with respect to the current practices of affected entities and differences in the impact of the CGTP final rule across the various sectors of the HCT/P industry.

A. Risks Associated with HCT/Ps

FDA has conducted an extensive search for information with which to quantitatively assess and characterize the risks associated with HCT/Ps, but has found very little information available. The primary reason for this lack of information is the absence of mandatory reporting requirements for adverse events, including the incidence of communicable disease transmission and graft failure, associated with HCT/Ps. The CGTP final rule will help to improve upon this situation by requiring entities that make HCT/Ps available for distribution to report to the agency any adverse reaction that meets the requirements of § 1271.350(a), as well as reports of HCT/P deviations required in § 1271.350(b). This information will be highly valuable to the agency in identifying and addressing areas of existing and emerging public health and safety risks associated with HCT/Ps. The available information regarding the risks associated with HCT/Ps known to the agency is summarized in the discussion that follows. Specific examples of risks associated with individual HCT/Ps are discussed in detail in section C of this analysis of economic impacts.

The HCT/P industry is currently growing and evolving rapidly. Since the CGTP proposed rule was published in January 2001, there have been significant increases in both the number of tissue donors and manufacturing establishments, as well as the number of HCT/Ps processed, distributed, and transplanted. Estimates of the current number of establishments in each sector of the HCT/P industry are presented in table 1b, along with recent information reflecting the approximate numbers of tissue donors and tissue products produced annually.

TABLE 1B.—NUMBERS OF HCT/P ESTABLISHMENTS, TISSUE DONORS AND PRODUCTS PRODUCED BY MAJOR INDUSTRY SECTOR

Type of HCT/P	Number of Establishments[1]	Number of Donors	Number of Products Produced Annually
Eye Tissue[2]	134	47,796	94,186
Conventional Tissue[3]	166	20,000	750,000
Hematopoietic Stem/Progenitor Cells[4]	425	5,700	6,031
Reproductive Tissue[5]	510	4,640	122,200

[1] Information obtained under the registration and listing final rule or provided by HCT/P industry professional associations. See section B.1 and table 3 of this analysis of economic impacts for additional details.
[2] EBAA, 1999.
[3] AATB, 1999.
[4] AABB/FACT, 1999.
[5] The American Society of Reproductive Medicine (ASRM), 1999.

One source of potential communicable disease transmission risk associated with HCT/Ps is a lack of standard quality assurance procedures and recordkeeping requirements intended to ensure compliance with such procedures. Currently, in every major sector of the HCT/P industry, professional organizations have in place standards specifying appropriate operating procedures that establishments should follow to ensure that the products produced are safe for use and of high quality. Individual establishments in the various sectors of the HCT/P industry may also apply for accreditation through these professional organizations, which periodically inspect member establishments to ensure that they are following the appropriate standards. However, as discussed in detail in V.B and C of this economic analysis, following industry standards and seeking accreditation through the professional organizations is voluntary, and the rates of compliance and accreditation within the various sectors of the HCT/P industry vary significantly. Furthermore, there are currently no comprehensive monitoring or enforcement mechanisms governing establishments that choose not to follow voluntary industry standards or seek accreditation, and that may produce and distribute for use HCT/Ps that may present a serious threat to public health and safety.

The agency is aware of numerous reports of adverse health events and several patient deaths that have been linked to HCT/Ps. Transplantation of tissue has resulted in transmission of viral, bacterial, fungal, and other diseases, although such instances are rare. Some of these adverse events have been associated with HCT/Ps produced by large entities that do not follow voluntary industry standards and are not accredited by their respective professional associations. In March of 2002, the CDC published the results of their investigation of 26 reported cases of tissue allograft-associated infection, one of which resulted in the death of the patient (Ref.1). The CDC concluded that of the 26 reported cases, ''14 (were) associated with a single tissue processor,'' and further suggested that their

* * * findings * * * have important implications for patient safety and indicate that current federal regulations and industry standards on processing and quality control methods need to be enhanced and implemented to prevent * * * allograft-associated infections.

Problems due to inadequate product processing and quality controls, contributing to post-operative infection and/or graft failure, are one category of the many potential causes of the reported adverse health events associated with HCT/Ps. Implementation of the CGTP final rule, by establishing an enforceable set of product quality assurance procedures and standards, is expected to reduce the risk of communicable disease transmission as well as the incidence of other types of adverse health events associated with HCT/Ps.

Recent information on the number of infections following surgery, incidence of communicable disease transmission, graft failures, and additional surgeries required as a result for various types of HCT/Ps is summarized in table 2 of this document. Although these numbers suggest that the risks associated with the various types of HCT/Ps are relatively low, it is important to consider the limitations of these data.

It is highly unlikely that the available data provide an accurate accounting of the true risks associated with HCT/Ps because there is currently no mandatory reporting requirement for adverse health events, including communicable disease transmission and graft failure, associated with tissues. Thus, the case reports that are known to the agency are almost certainly not representative of the risks associated with HCT/Ps, because a significant number of these events may go unreported. In the eye banking industry, the EBAA requests that adverse event information be voluntarily reported, but acknowledges that not all members provide this information. The AATB does not request information on the number of adverse events reported to accredited conventional tissue banks. Further, the New York Department of Health indicated that they know of no entity that collects information on graft failures or repeat surgeries due to complications associated with musculoskeletal tissues. Thus, despite a significant effort on the part of the agency, very little information with which to identify and quantify the risks associated with various types of HCT/Ps was found. In summary, the limited information presented in this analysis of impacts is not likely representative of the true risks associated with HCT/Ps, because no mandatory adverse event reporting requirements exist, the information that is available is reported voluntarily and, in some sectors of the tissue industry, the necessary information is not available because it is not collected by any source.

TABLE 2.—SUMMARY OF AVAILABLE HCT/P RISK INFORMATION[1]

Type of HCT/P	Number of Transplants	Number of Infections	Number of Graft Failures	Additional Surgeries Required
Ocular (Eye)[2]	33,035	9	37	37
Musculoskeletal[4]	NDF[3]	52	NDF	4
Heart Valve Allografts[5]	4,000	26	41	41
Hematopoeitic Stem/Progenitor Cells; Peripheral Blood[6]	18,123 (in 1997)	NDF	NDF	NDF
Hematopoeitic Stem/Progenitor Cells; Cord Blood[7]	2000 (from 1988 to 2002, inclusive)	NDF	NDF	NDF

[1] Annual data except as noted otherwise.
[2] EBAA, 2001 Statistical Report.
[3] NDF: Denotes No Data Found or Available.
[4] AATB, 2001.
[5] FDA, CDRH, Office of Surveillance and Biometrics, 2001.
[6] *Transfusion*, vol. 42, 2002.
[7] *Current Opinion in Oncology*, vol. 14, No. 2, March 2002.

The agency obtained additional information on the risks associated with HCT/Ps by reviewing establishment inspection reports (EIRs) filed by agency inspectors. The following information summarizes some of the inspector's observations made in the course of their inspections of establishments processing human tissues. This information was obtained from a manual search of approximately 150 EIR reports filed in 2000 and 2001, and reflects observations from 15 of the 150 EIRs that were not citable under 21 CFR part 1271, but would be citable under 21 CFR part 1271. As such, this discussion is not a comprehensive assessment of the results of FDA inspections of HCT/P processing establishments. Instead, it is intended to provide an illustration of the type of processing and quality assurance problems that currently exist in the tissue industry, and that would be addressed through implementation of the CGTP final rule.

Failure to validate procedures for various stages of HCT/P processing was identified in 8 of the 15 reports. More specifically, observations included failure to validate procedures for the prevention of infectious disease contamination and cross-contamination during processing, and failure to prepare written procedures for designating and identifying quarantined tissue. Failure to document the destruction or disposition of human tissue, failure to designate and identify the person responsible for making the determination that an HCT/P was suitable for transplantation, and/or failure to accompany quarantined tissue with records indicating the tissue was not determined to be suitable for transplantation were identified in 5 of the 15 reports. Failure to maintain adequate records of each significant step in the processing of human tissues and/or performance of infectious disease screening, as well as failure to maintain accurate records thereof, were cited in 6 of the 15 inspection reports. Finally, failure to prepare and follow written procedures for all significant steps for obtaining, reviewing, and assessing the relevant medical records of tissue donors, or failure to provide along with dispensed tissue a summary of the records of the donor eligibility determination, were cited in 7 of the 15 inspection reports. Although this summary of examples of FDA inspector's observations related to provisions under part 1270 is not comprehensive, it does indicate the type of procedures and quality control problems observed in HCT/P processing establishments in 2000 and 2001. Each example could have an adverse impact on the HCT/P, and all are further addressed by various provisions of the CGTP final rule.

To gain additional insights into the risks associated with HCT/Ps, FDA also reviewed reports of adverse events associated with human tissue products submitted through the MedWatch

system. Between 2000 and 2001, FDA received 21 voluntary MedWatch reports of problems associated with HCT/Ps. Because there is no mandatory requirement for reporting adverse reactions involving tissue products, the extent to which these reported events are representative of the risks associated with HCT/Ps during this period is unclear. It is likely, however, that a significant number of adverse events associated with HCT/Ps are unreported under the current voluntary MedWatch system. The 21 reported adverse events included: 4 patient deaths (3 of which were probably due to underlying disease and not directly attributable to HCT/Ps); 5 life-threatening situations; 5 surgical or other medical interventions; 2 cases of permanent disability; 9 additional hospitalizations; and 7 cases of mold contamination of HCT/P packaging material. Many of the potential underlying causes of these voluntarily reported adverse events are addressed by various provisions of the CGTP final rule, implementation of which is expected to reduce communicable disease transmission risks and the number of adverse events associated with the various types of HCT/Ps.

B. Estimated Cost Impact

With the CGTP final rule, FDA is furthering completion of the set of proposals that represent a comprehensive new system for regulating the rapidly evolving HCT/P industry. Manufacturers of HCT/Ps may need to make certain changes to their operations to comply with this rule, such as creating new procedures revising existing procedures, and providing additional documentation. This final rule, in its entirety, affects several types of entities involved in the manufacture of HCT/Ps including eye banks, conventional tissue banks and establishments processing hematopoietic stem/progenitor cells. As explained elsewhere in this preamble, Assisted Reproductive Technology (ART) establishments and semen banks are subject only to the inspection and enforcement provisions of the CGTP final rule as they apply to donor eligibility requirements under subpart C. As such, reproductive tissue establishments will be only minimally affected by this final rule.

Information obtained under the registration final rule forms the basis for FDA's estimates of the number of affected eye banks and conventional tissue banks. The agency's estimates of the number of affected eye banks, hematopoietic stem/progenitor cell establishments, ART establishments, and semen banks rely heavily on information obtained from various professional organizations associated with the HCT/P industry. Where good statistical data are not available, FDA's cost impact estimates have incorporated the quantitative judgments of individual experts identified through contacts with HCT/P industry professional associations. Because of the lack of comprehensive data with which to characterize patterns of current practice within each affected industry sector, and the importance of this data for development of an accurate assessment of cost impact, FDA requested detailed industry comment on the number of establishments involved in the manufacture of HCT/Ps, and the net change in quality assurance efforts needed for those establishments to comply with the CGTP proposed rule. To the extent possible, this information has been incorporated into FDA's analysis of the economic impact of this final rule.

1. The Number and Type of Entities Affected

The analysis of the economic impact of this final rule is organized around four major subgroups: Eye banks, conventional tissue banks, hematopoietic stem/progenitor cell establishments, and reproductive tissue establishments. The number of establishments and the percentage of establishments that follow current industry standards are summarized in table 3 of this document. In estimating net new costs for eye banks, conventional tissue banks and hematopoietic stem/progenitor cell establishments, it is critical to account for establishment compliance with existing industry standards. In a number of these HCT/P sectors, current industry standards for many manufacturing operations meet or exceed the specifications in this final rule. Establishments following those standards will experience very little impact in complying with the new FDA standards.

As presented in table 3 of this document, FDA has a record of 134 registered establishments listing eye tissue including 96 eye banks, approximately 93 of which are currently accredited by the EBAA. According to industry experts, virtually all operating eye banks currently comply with EBAA medical and procedural standards for quality control. For affected eye banks, the incremental costs associated with this final rule result from additional quality assurance steps and process documentation as specified under the CGTP final rule.

FDA has a record of 166 registered tissue banks involved in the manufacture of other conventional HCT/Ps, e.g., skin allografts, bone allografts, fascia, tendons and ligaments (hereafter referred to as ''conventional tissue banks''). The AATB lists approximately 75 accredited tissue banks and projects another 40 to 60 members unaccredited. Industry sources report that approximately 75 to 80 percent of these establishments currently follow the voluntary standards established by the AATB. For these establishments, there will be some additional cost associated with review of this final rule and with alignment of their current SOPs with FDA's new requirements. There may also be some additional recurring cost, where documentation and quality control required under the CGTP final rule extend beyond current practice. For the remaining 20 to 25 percent of establishments not following the AATB standards, the cost of compliance will be somewhat higher. These establishments may need to establish more formal procedures and quality control measures, and may need to devote additional staff hours to performing these procedures and processing controls.

Establishments that produce hematopoietic stem/progenitor cells from peripheral blood or from umbilical cord blood will also be affected by this final rule. FDA finds that available data with which to estimate the number of peripheral blood stem/progenitor cell (PBSC) establishments and evaluate current practices are quite limited, and the actual number of PBSC establishments may range from 200 to 400. As of April 2002, CBER has a record of 178 voluntarily registered establishments listing ''stem cell'' as a type of product or establishment. The National Marrow Donor Program (NMDP), which includes establishments that recover PBSCs, lists approximately 92 donor centers and 113 collection centers. Approximately 150 establishments involved with PBSCs are currently accredited by the AABB and an estimated 107 are accredited by the Foundation for the Accreditation of Cellular Therapy (FACT). Industry sources estimate that 80 of these establishments are seeking dual AABB/FACT accreditation, suggesting an unduplicated count of approximately 200 PBSC establishments assumed to be accredited by AABB and/or FACT. However, the number and manufacturing practices of nonaccredited establishments are unknown. The International Bone Marrow Transplant Registry/Autologous

Blood and Marrow Transplant Registry (IBMTR/ABMTR) estimates that the total number of peripheral blood or bone marrow establishments may be as high as 400 (e.g., 200 more than the number estimated to be accredited by AABB and/or FACT), but the number of IBMTR/ABMTR-estimated establishments that actually process peripheral blood (as opposed to bone marrow) is uncertain. For the purposes of this analysis, FDA has assumed that 400 PBSC establishments will be affected by this final rule.

Although there is no single national organization that keeps track of the number of establishments for umbilical cord blood banking, FDA estimates that there are approximately 25 cord blood banks currently operating in the United States. These establishments would also seek accreditation through FACT or AABB. Based on this information, the agency estimates that a total of 425 establishments involved in manufacturing hematopoietic stem/progenitor cells would be affected by this final rule.

In addition, 67 establishments produce licensed biological products or approved medical devices that are currently regulated under the act and/or section 351 of the PHS Act, but would be subject to the provisions of this final rule. The impact of CGTPs on these firms is expected to be minimal because they are already subject to existing CGMP regulations for drugs or QS regulations for medical devices. Those requirements are largely consistent with the requirements of this final rule.

Finally, the inspection and enforcement provisions of this final rule, as they apply to donor eligibility requirements under subpart C, will affect establishments involved with reproductive tissue, primarily ART establishments and semen banks. For purposes of this discussion, references to ART establishments include infertility clinics, as well as andrology and embryology laboratories. The ASRM has a membership of approximately 400 fertility centers, 370 of which have provided reports for the 1999 Society for Assisted Reproductive Technology registry (Ref. 29). The ASRM also has a 1996 list of approximately 110 semen banks operating in the United States. Based on conversations with consultants, most ART and commercial semen banking establishments currently adhere to industry standards similar to those in the CGTP final rule. There are currently 11 semen banks accredited by the AATB and, according to industry consultants, the remaining commercial semen banks are licensed by State health agencies, including the California Department of Health and the New York Department of Health.

Semen banks and andrology laboratories at ART establishments are also regulated under the Clinical Laboratory Improvement Amendment (CLIA) of 1988.

The Committee on Laboratory Accreditation and JCAHO also inspect embryo laboratories for accreditation. The requirements for accreditation by the College of American Pathologists (CAP), which accredits ART establishments, closely resemble those in the CGTP final rule, with a few exceptions. Consultants estimate that as many as 80 percent of ART establishments may currently comply with the CAP requirements.

TABLE 3.—ESTIMATED PERCENTAGE OF ESTABLISHMENTS THAT FOLLOW VOLUNTARY INDUSTRY STANDARDS

Affected Industry	Relevant Voluntary Industry Standards	Percentage of Firms Following Voluntary Industry Standards
Eye Tissue: 134 FDA Registered Establishments	EBAA	100 %
Conventional Tissue: (e.g., pericardium, dura mater, heart valves, skin allograft, bone allograft, fascia, tendons, ligaments, other viable) 166 FDA Registered Establishments	AATB	75 to 80%
Stem/Progenitor Cells: Peripheral Blood (PB): 400 establishments Cord Blood (CB): 25 establishments	 AABB or FACT AABB or FACT	 85 % of accredited PB establishments 100 % of all CB establishments
Reproductive Tissue: Semen Banks: 110 establishments	AATB; CAP accreditation;State Licensed (e.g., NY, CA); and/or CLIA-certified	20 largest establishments (accounting for 95% of total production)
Reproductive Tissue: ART Establishments: 400 establishments	CAP accreditation; State Licensed (e.g., NY, CA); ASRM guidelines	80 %

2. Estimated Impact on Eye Banks, Conventional Tissue Banks and Hematopoietic Stem/Progenitor Cell Establishments

In the sections that follow, the agency considers each of the provisions of this final rule and estimates the impact on establishments in those sectors of the HCT/P industry subject to CGTPs in their entirety. The impact analysis distinguishes expected cost impacts based on both facility size and estimated rates of current adherence to voluntary industry standards. Based on size standards established by the U.S. Small Business Administration (SBA), a small establishment in this industry sector (the North American Industry Classification Scheme (NAICS) code 621991, Blood and Organ Banks) has annual receipts of less than $8.5 million (Refs. 21 and 22).

TABLE 4.—ESTIMATED COST PER ESTABLISHMENT AND ESTIMATED PERCENTAGE OF ESTABLISHMENTS AFFECTED BY THE CGTP FINAL RULE[1]

21 CFR Section	Title	Eye Tissue Establishments	Conventional Tissue Sm./Lrg.	Stem/Progenitor Cell Establishments
1271.150	Current Good Tissue Practice Requirements	—	—	—
1271.155	Exemptions and Alternatives	—	—	—
1271.160	Establishment and Maintenance of a Quality Program: General			
	-Establishment with Minor Deficiencies	$511 (95%)	$511/$1,278 (23%)	$511 (80%)
	-Establishment with Major Deficiencies	$2,498 (5%)	$2,498/$4,832 (5%)	$2,498 (5%)
	-Cost for Additional Quality Control Work	$1,344 (95%)	$1,344 (23%)	$1,344 (80%)
(b)(2)	Procedures for Sharing Information	$380 (95%)	$760/$2,172 (23%)	$760 (80%)
(b)(3)	Corrective Actions	$456 (95%)	$912 (23%)	$912 (80%)
(b)(6)	Investigations	$2,214 (95%)	$2,214 (23%)	$2,214 (80%)
(c)	Audits	$456 (95%)	$912/$1,824 (23%)	$912 (80%)
(d)	Validate Custom Computer Software	$2,160 (10%)	$2,160 (10%)	$2,160 (10%)
1271.170	Organization and Personnel:			
(b)	Competent Personnel	—	$15,560 (23%)	$15,560 (95%)
(c)	Training	—	$2,476/$3,104 (23%)	$2,476 (95%)
1271.180	Procedures—General Requirements	$9,120 (5%)	$9,120 (23%)	$9,120 (95%)
1271.190	Establishments:			
(d)(1)	Cleaning and Sanitation Procedures	$348 (5%)	$348/$532 (23%)	$348 (95%)
(d)(2)	Cleaning and Sanitation Records	—	—	—
1271.195	Environmental Control and Monitoring:			
(a)	Environmental Control	—	$348/$532 (23%)	$348 (95%)
(b)(c)	Inspections and Monitoring	$1,000 (5%)	—	$1,000 (95%)
(d)	Records	$174 (95%)	$174/$348 (23%)	$174 (95%)
1271.200	Equipment:			
(b)	Procedures/Schedules—Cleaning, Sanitizing and Maintenance	—	$1,460/$2,979 (23%)	$1,460 (95%)
(c)	Calibration	—	$1,460/$2,979 (23%)	$1,460 (95%)
(d)	Inspections	$216 (95%)	$432/$684 (23%)	$216 (95%)
(e)	Records			
	-of Cleaning, Sanitizing and Calibration Activities	$174 (95%)	$348/$696 (23%)	$174 (95%)
	-of the Use of Each Piece of Equipment	$696 (95%)	$1,392/$2,784 (23%)	$1,392 (95%)
1271.210	Supplies and Reagents:			
(a)	Verification	$131 (95%)	$348/$532 (23%)	$348 (95%)
(c)	In-house Reagents	—	$348/$532 (23%)	$348 (95%)
(d)(1)	Records of Receipt, Verification, and Lot	$174 (95%)	$174/$348 (23%)	$174 (95%)
1271.220	Process Controls:			
	In-Process Monitoring Procedures	$380 (95%)	$380/$1,086 (23%)	$760 (95%)
1271.225	Process Changes:			
	Validation of Process Changes	$760 (95%)	$760/$2,172 (23%)	$760 (95%)
	Records/Documentation	$456 (95%)	$456/$912 (95%)	$456 (95%)
1271.230	Process Validation:			
(a)	General	$1,700 (95%)	$1,700 (95%)	$1,700 (95%)
	Procedures	$1,520 (95%)	$760/$2,172 (95%)	$1,520 (95%)
(c)	Validation/Revalidation of Process Changes	$850 (95%)	$1,700 (95%)	$1,140 (95%)
1271.250	Labeling Controls:			
(a)(b)	Procedures	$380 (5%)	$380/$1,086 (5%)	$380 (95%)
1271.260	Storage	—	—	—
1271.265	Receipt, Pre-Distribution Shipment and Distribution:			
	Recordkeeping and Documentation	$864 (5%)	$1,728/$3,456 (5%)	$3,456 (5%)
(a)	Procedures—Receiving Activities	—	$380/$1,086 (23%)	$760 (95%)
(c)	Procedures—Availability for Distribution	—	$380/$1,086 (23%)	$760 (95%)
(d)	Packaging and Shipping	$1,392 (95%)	$1,392 (95%)	$576 (95%)
(f)	Procedures—Return to Inventory	—	$348/$532 (23%)	$348 (95%)
1271.270	Records:			
(a)	General	$728 (95%)	$728/$1,618 (95%)	$728 (95%)
(b)	Records Management System	$3,040 (95%)	$3,040/$6,080 (23%)	$3,040 (95%)

TABLE 4.—ESTIMATED COST PER ESTABLISHMENT AND ESTIMATED PERCENTAGE OF ESTABLISHMENTS AFFECTED BY THE CGTP FINAL RULE[1]—Continued

21 CFR Section	Title	Eye Tissue Establishments	Conventional Tissue Sm./Lrg.	Stem/Progenitor Cell Establishments
(d)	Length of Retention	$18 (5%)	$18 (23%)	$18 (95%)
1271.290	Tracking:			
(b)(c)	System of Product Tracking: General Requirements	$760 (5%)	$380/$1,086 (23%)	$380 (95%)
(d)(e)	System of Product Tracking: Specific Requirements	$1,728 (5%)	$3,456/$6,912 (23%)	$3,456 (95%)
(f)	Consignees	$1,520 (5%)	$1,520 (23%)	$1,520 (95%)
1271.320	Complaint File:			
(a)	Procedures	$131 (95%)	$348/$532 (23%)	$348 (95%)
(b)	Complaint File	—	—	—
(c)	Review and Evaluation of Complaints	$608 (95%)	$608/$1,216 (23%)	$608 (95%)
1271.350	Reporting	$592 (100%)	$592 (100%)	$592 (100%)
1271.370	Labeling	—	—	—
1271.400	Inspections			
(a)	General	$768 (100%)	$768 (100%)	$768 (100%)
1271.420	HCT/Ps Offered for Import	—	—	—
1271.440	Orders of Retention, Recall, Destruction and Cessation of Manufacturing.	—	—	—

[1] Only subsections expected to impose new compliance costs for a particular industry sector are shown. No cost is estimated for a subsection if analysis revealed that the requirements: (1) do not apply, (2) have no new cost impact, or (3) are met by another subsection of the CGTP final rule. Estimated noncompliance rates are in parentheses.

As indicated by the information in table 4 of this document, the impact of the CGTP final rule varies significantly, depending upon the sector of the HCT/P industry, size of the affected entity and the particular provision. For many of the CGTP provisions, the establishment level impact will entail development of new procedures, or revision of existing procedures. The scope and degree of complexity of these changes will vary. FDA expects that the staff typically involved in the development, revision, and finalization of establishment procedures will include technicians, clerical staff, lab supervisors, and the lab director. Although FDA did not specify personnel requirements for individual provisions of the CGTP final rule, for purposes of industry-wide estimation, the agency's cost analysis relies on standardized estimates of the type of personnel, level of effort, and hourly labor cost for revising or establishing each type of procedure. Table 5 of this document summarizes the agency's assumptions, which are based on published wage and benefits data and input from HCT/P industry consultants.[1]

TABLE 5.—ESTIMATED LEVEL OF EFFORT AND COST PER PROCEDURE REVISED OR PREPARED TO COMPLY WITH THE CGTP FINAL RULE

Category:	Minor Procedures		Major Procedures	
	Revise Existing	Prepare New	Revise Existing	Prepare New
Small Establishment				
Total level of staff effort	3 hrs.	7 hrs.	8 hrs.	16 hrs.
Cost (rounded)	$131	$348	$380	$760
Large Establishment				
Total level of staff effort	5 hrs.	13 hrs.	27 hrs.	54 hrs.
Cost (rounded)	$192	$532	$1,086	$2,172

[1] A detailed presentation of level of effort and cost assumptions for nonreproductive tissue establishments is provided in FDA's *Cost Impacts of the Proposed Current Good Tissue Practice Rule on Eye Banks, Conventional Tissue Banks, and Stem Cell Facilities: Background Paper*, April 1999, and for reproductive tissue facilities in *Cost Impacts of the Proposed Current Good Tissue Practice Rule on Semen Banks and ART Facilities*, February 1999, prepared by Eastern Research Group (ERG), Inc. These documents are available in docket 97N–484P.

The analysis of cost impacts for HCT/P industry sectors subject to CGTPs in their entirety is summarized in the following discussion of the rule's individual provisions, and the expected type and extent of industry impact. The pertinent section of the final rule is noted to facilitate reference to the related cost estimates presented in table 4 of this document.

a. Section 1271.150—current good tissue practice: general. The final rule requires manufacturers of HCT/Ps to follow CGTPs. Section 1271.150(a) provides an overview of CGTPs but does not present specific compliance requirements. The specific requirements are addressed in subsequent sections. Section 1271.150(b) lists the core CGTP requirements, and § 1271.150(c) addresses compliance with applicable requirements for those entities subject to CGTPs. Section 1271.150(d) explains the relationship between the CGTP rule and regulations specifically applicable to biological drugs or devices, and paragraph (e) defines the term ''where appropriate'' in relation to the rule. Section 1271.150(b) through (e) will not generate any compliance costs for the HCT/P industry because no specific requirements are specified.

b. Section 1271.155—exemptions and alternatives. The CGTP final rule allows establishments to request an exemption or alternative from FDA for certain provisions of the rule. There is currently no basis for predicting the number of industry requests for exemptions or alternatives, or for predicting the effect of these actions on compliance costs. Because of a high degree of similarity between CGTPs and current voluntary industry standards, FDA anticipates that very few establishments will consider it appropriate to be exempted from the provisions of this final rule.

c. Section 1271.160—establishment and maintenance of a quality program. The final rule requires that establishments establish and maintain a quality program. The quality program must include: Procedures relating to core CGTP requirements, procedures for exchanging information with other establishments known to have recovered cells or tissue from the same donor, appropriate corrective actions related to core CGTP requirements, proper training and education of personnel involved in activities related to core CGTP requirements, appropriate monitoring systems, investigation and documentation of HCT/P deviations related to core CGTP requirements, audits, computer software validation or verification, and other procedures specific to the quality program. Several of these functions are further specified in subsequent provisions of the rule, and the impact is estimated in the context of those provisions.

In general, FDA anticipates that almost all of the establishments in the affected industry sectors have the appropriate facilities, equipment, and systems to support a quality program, but only those already following industry standards are expected to have comprehensive quality programs in place. Some establishments may need to upgrade their quality program for several of the CGTP requirements. These include procedures for sharing information, corrective actions, and investigations. Further, some establishments may need to take additional steps to administer corrective actions and conduct investigations if they currently do so only when major deficiencies arise.

Although the sharing of information is an industry-wide practice, some small establishments, particularly those not following current industry standards, may not have written procedures and forms for this task. FDA estimates that 95 percent of eye banks, 23 percent of conventional tissue banks not following the current AATB standards, and 80 percent of the hematopoietic stem/progenitor cell establishments not following the FACT or AABB standards, will need to prepare a major procedure to address this requirement.

Although FDA anticipates that most industry establishments take steps to administer corrective actions and conduct investigations, some may currently do so only when major deficiencies arise.

FDA estimates that 95 percent of eye banks, 23 percent of conventional tissue banks, and 80 percent of hematopoietic stem/progenitor cell establishments not following industry standards will need to invest additional time to meet these new requirements. The incremental time burden to administer corrective actions and document these activities is estimated to be an additional 1/2-hour per month of laboratory director time at establishments that already perform this activity to a lesser extent, and an additional hour per month at all other establishments that will be newly affected by this provision. As discussed in the background papers prepared by FDA and Eastern Research Group (ERG), and shown in table 4 of this document, for newly required investigations in tissue establishments, FDA estimates an additional cost per year of $2,214 for an additional 2 hours per month for the laboratory director to investigate and document deficiencies, and an additional 1/2 hour each for the laboratory supervisor and lab technician to participate in the investigations.

A number of establishments will also need to institute other requirements of the quality program, including periodic audits, computer software validation or verification, and procedures specific to the quality program. Audits are part of the industry standards published by the AATB, EBAA, FACT, and AABB. However, some establishments following these standards may need to do some additional recordkeeping, and establishments not following standards will need to begin to conduct audits. Referring to table 4 of this document, FDA assumes that up to 95 percent of eye banks will increase their audit efforts, including additional lab director time to prepare for and perform the periodic audit. An estimated 23 percent of conventional tissue banks will allocate additional resources for audits, with a higher allocation of hours at larger establishments, to prepare for, and to conduct, the audit. For hemapoietic stem/progenitor cell establishments, FDA estimates that there will be no additional auditing required at establishments following FACT or AABB standards, but an estimated 80 percent of establishments not following industry standards will need to spend additional time to prepare for and to conduct periodic audits.

Section 1271.160 of the CGTP final rule further stipulates that establishments must validate or verify, as appropriate, the computer software used in their operations when it is used in the performance of core (good tissue practice (GTP) functions. Validation would be required for custom software used in core GTP functions. However, for off the shelf commercial software packages (e.g., for data storage and retrieval, recordkeeping, etc.) used as intended by the software manufacturer, it would be adequate for the establishment, when using such products in the performance of core GTP functions, to verify the product's performance. Such products are already validated or verified by the software vendor.

FDA assumes that none of the affected establishments currently validate or verify their custom software and that approximately 10 percent of eye banks, conventional tissue banks and hematopoietic stem/progenitor cell establishments have developed custom software that will require full validation or verification under this final rule. Because we received no specific comments regarding these assumptions in response to the proposed rule, we have retained them here. Although the

scope of such work can vary, FDA estimates that the custom software in use has a limited scope of application, and that an average of 60 hours of work by the laboratory supervisor will be required to validate or verify custom computer software at an establishment. Detailed presentations of these assumptions are provided in section 2.4.3 of the background papers (see footnote 1 of this document) by FDA and ERG.

The last requirement for the quality control program is for procedures that stipulate how the quality program should be operated. Industry consultants indicated that establishments have quality systems in place, but that most establishments are not aware of some minor elements of CGTPs that should be included in their procedures. Consequently, inspectors for accreditation groups often find a few deficiencies during initial visits. FDA estimates that about 95 percent of eye banks, 23 percent of conventional tissue banks, and up to 80 percent of hematopoietic stem/progenitor cell establishments will have minor deficiencies that will require them to revise one minor and one major procedure. In addition, FDA estimates that 5 percent of all eye banks, and conventional tissue banks and hematopoietic stem/progenitor cell establishments not following voluntary industry standards may identify major deficiencies, and will need to prepare five minor procedures and one major procedure to address those problems.

The agency further assumes that establishments may generally need to perform some additional quality control work to comply with the quality program requirements in the CGTP final rule. Although some tasks will not require any additional time to perform, FDA estimates that approximately 1 hour per month each for the laboratory director and supervisor may be needed. The agency estimates that 95 percent of all eye banks, 23 percent of conventional tissue banks, and approximately 80 percent of hematopoietic stem/progenitor cell establishments will need to allocate additional staff time for this purpose.

d. Section 1271.170—personnel. This final rule requires establishments to employ sufficient personnel with the necessary education, experience, and training to ensure competent performance of their assigned functions. The EBAA, AATB, FACT, and AABB standards for quality assurance all include provisions for appropriate personnel qualifications and training, and recordkeeping related to this requirement. It is expected that most eye banks, conventional tissue banks and hematopoietic stem/progenitor cell establishments will already be compliant with these provisions of the CGTP rule. Those establishments in the conventional tissue and hematopoietic stem/progenitor cell manufacturing sectors that do not follow industry standards will incur new costs. The cost of this staffing effort is estimated to be approximately $15,560 per affected establishment.

FDA anticipates that the 23 percent of conventional tissue banks and 95 percent of hematopoietic stem/progenitor cell establishments not following industry standards will incur new training costs to comply with the personnel provisions of the CGTP final rule. For a small tissue establishment, these costs are estimated to average $2,476. The CGTP final rule also requires that records of personnel qualifications and training be maintained, but because existing industry standards address personnel recordkeeping, FDA assumes that the cost to comply with this requirement will be negligible. Details of these assumptions are provided in section 2.4.4 of the background papers (see footnote 1 of this document) by FDA and ERG.

e. Section 1271.180—procedures: general requirements. The CGTP final rule requires establishments to establish and maintain written procedures appropriate to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps. FDA anticipates a negligible incremental cost for most establishments following industry standards, and an additional 120 hours of laboratory director time for establishments not following the current industry standards. FDA estimates that 5 percent of eye banks will need to expand their current efforts, and that 23 percent of conventional tissue banks and 95 percent of hematopoietic stem/progenitor cell establishments will incur new costs.

f. Section 1271.190—facilities. This final rule stipulates a number of requirements regarding facilities covering operations, size, construction, location, lighting, ventilation, plumbing, drainage and access to sinks and toilets. A facility used in the manufacture of HCT/Ps must be of suitable size, construction, and location to prevent contamination of HCT/Ps with communicable disease agents and to ensure orderly handling of HCT/Ps without mix-ups. Cleaning and sanitation requirements are also outlined, including requirements for written procedures, schedules, and documentation of these activities.

Based on discussions with industry experts, FDA estimates that nearly all establishments that follow industry standards will not incur any new costs under these provisions of the CGTP final rule. However, some establishments that generally adhere to cleaning standards do not have written procedures. Thus, FDA estimates that 5 percent of all eye banks, in addition to 23 percent of the conventional tissue banks and 95 percent of all hematopoietic stem/progenitor cell establishments, will incur the cost of writing a minor procedure for cleaning. The facilities provision of the CGTP final rule also requires that records of cleaning be maintained. This requirement is met by establishments following industry standards, and is expected to have a negligible impact on establishments not following the current voluntary standards.

g. Section 1271.195—environmental control and monitoring. Where environmental conditions could reasonably be expected to cause contamination or cross-contamination, or accidental exposure of HCT/Ps to communicable disease agents, environmental conditions must be adequately controlled. The final rule also requires that environmental control systems be monitored and periodically inspected, and that environmental control and monitoring activities be documented. The impact of this provision of the CGTP rule varies by industry sector. For affected eye banks, the EBAA standards already contain similar provisions, however, some additional costs may be incurred for periodic inspection of environmental control systems and for keeping records of environmental control and monitoring activities. It is estimated that 5 percent of eye banks may incur new costs for inspection of equipment. FDA anticipates that conventional tissue banks following AATB standards will experience no new costs, but that the remaining 23 percent of establishments will need to prepare a minor procedure for control and monitoring of ventilation and air filtration.

The current FACT and AABB standards do not require written procedures for environmental control and monitoring. FDA therefore estimates that 95 percent of all hematopoietic stem/progenitor cell establishments will need to develop a minor procedure for control and monitoring of ventilation and air filtration systems to comply with the CGTP rule. However, because the industry standards do provide for appropriate environmental controls, FDA assumes that some establishments

are performing the necessary control and monitoring activities. The agency estimates that as many as half of the establishments currently following industry standards may already be conducting routine inspections of their environmental control equipment. It is assumed that the remaining 50 percent of those establishments, and 95 percent of hematopoietic stem/progenitor cell establishments assumed not to be following industry standards, will incur additional costs to periodically inspect equipment and perform recordkeeping related to environmental control. Table 4 of this document provides estimates of cost per establishment associated with these efforts.

h. Section 1271.200—equipment. This final rule requires that appropriate equipment be used in processing HCT/Ps to prevent the introduction, transmission, or spread of communicable disease. Cleaning, sanitizing, maintenance, and calibration of equipment must be performed according to established schedules and procedures; equipment must be regularly inspected for adherence to applicable procedures and schedules; and all such activities must be documented. In addition, establishments must keep records of each use of each piece of equipment, including the identification of each HCT/P manufactured with that piece of equipment.

The standards related to equipment, as specified by AATB, EBAA, FACT, and AABB, generally address maintenance procedures, and recordkeeping related to maintenance. However, this final rule extends beyond industry standards of EBAA, FACT, and AABB in the areas of equipment inspection and recordkeeping. Based on information provided by industry sources, FDA believes that some of the larger HCT/P establishments may already be performing the required equipment inspection and recordkeeping.

FDA therefore estimates that 95 percent of all eye banks will allocate an additional 1/2-hour per month for the laboratory supervisor to inspect equipment, an additional 1/2-hour per month of technician time to document equipment cleaning and calibration, and 2 additional hours per month for a technician to record each use of the equipment.

The estimated 23 percent of conventional tissue banks that currently do not follow AATB standards will also incur new costs related to the equipment provisions. FDA estimates that small establishments will prepare one minor procedure for calibration, and for cleaning and other maintenance for each of six pieces of equipment. In addition, small establishments will allocate an additional hour per month of lab supervisor time for routine inspection of equipment, an additional hour per month of technician time for documentation of cleaning and calibration, and 4 hours per month of technician time to record each use of the equipment. FDA estimates that large establishments will need to write minor procedures for each of eight pieces of equipment, will allocate an additional 2 hours per month of lab supervisor time for routine inspection of equipment, an additional 2 hours per month of technician time to record cleaning and calibration activities, and an additional 8 hours of technician time per month to record each use of each piece of equipment. It is anticipated that establishments simultaneously preparing multiple procedures related to equipment will realize some economies of scale because of similarities across procedures. This is expected to result in a savings of 30 percent in the total amount of staff time required to prepare six to eight minor equipment maintenance procedures.

It is expected that hematopoietic stem/progenitor cell establishments will also be required to perform additional work to align current practice with the CGTP requirements. Current FACT procedures provide for routine maintenance and calibration of equipment. In addition, the AABB standards recommend that SOPs be established for proper equipment maintenance and monitoring. To further develop procedures to address routine maintenance and recordkeeping under the CGTP rule, FDA estimates that 95 percent of all hematopoietic stem/progenitor cell establishments will prepare a minor procedure for calibration of each of six pieces of equipment. In addition to the preparation of procedures, lab personnel will be involved in carrying out the necessary maintenance work, estimated to require an additional 1/2 hour of lab supervisor time per month for routine inspection of equipment, an additional 1/2 hour per month for lab technicians to document cleaning and calibration work, and an additional 4 hours per month of lab technician time to record each use of equipment. In addition, most cell establishments that do not currently follow FACT or AABB standards will incur the cost of preparing a minor procedure for cleaning and sanitizing, and for routine maintenance of each of six pieces of equipment. Section 2.4.8 of the FDA and ERG background papers (see footnote 1 of this document) provide detailed presentations of these assumptions.

i. Section 1271.210—supplies and reagents. The CGTP rule requires manufacturers to verify that supplies and reagents used in the manufacture of HCT/Ps meet specifications designed to prevent circumstances that increase the risk of introduction, transmission, or spread of communicable disease. Verification of quality may be accomplished by the establishment that uses the supply or reagent, or the vendor of the supply or reagent. This final rule also requires documentation of the receipt and verification of supplies or reagents used in HCT/P processing, and of the lot of supply or reagent used in the manufacture of each HCT/P.

The existing industry standards address some or all of these activities, and the estimated impact per establishment varies accordingly. EBAA standards specify that sterilized supplies and reagents must contain sterilization dates and method, or appropriate expiration dates. However, the agency estimates that up to 95 percent of eye banks will need to devote additional resources to receipt and verification activities, and will devote additional staff time to recording the receipt of supplies and reagents. Similarly, FACT and AABB standards contain provisions for quality control in the storage, handling and use of supplies and reagents, including maintenance of records. However, FDA expects that approximately 95 percent of hematopoietic stem/progenitor cell establishments will expand on their current supply and reagent related recordkeeping to comply with these CGTP provisions.

The current AATB standards address most of the requirements for supplies and reagents included in the final rule. FDA assumes that the estimated 23 percent of conventional tissue establishments that do not follow these standards will require additional resources for in-house reagent receipt and verification, and will devote additional staff time to keeping records of the receipt and verification of supplies and reagents. The estimated costs per establishment for these provisions are presented in table 4 of this document.

j. Section 1271.215—recovery. The CGTP final rule requires that each HCT/P be recovered in a way that does not cause contamination or cross contamination during recovery, or otherwise increase the risk of the introduction, transmission, or spread of

communicable disease through the use of the HCT/P. Because this section does not impose any specific requirements it is not expected to impose any identifiable compliance costs.

k. Section 1271.220—processing and process controls. The CGTP final rule requires establishments to process HCT/Ps in a way that does not cause contamination or cross-contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease. An establishment processing HCT/Ps is responsible for ensuring that each in-process HCT/P is controlled until the results of any required inspections, testing, verification activities or approvals are received and documented. The standards for tissue banking specified by the AATB include activities to address these process controls, but the EBAA, FACT, and AABB standards do not include specific requirements for in-process monitoring. FDA estimates that 95 percent of eye banks, 23 percent of conventional tissue banks, and 95 percent of hematopoietic stem/progenitor cell establishments will need to prepare a minor procedure related to process monitoring.

l. Section 1271.225—process changes. This final rule requires establishments to verify or validate any changes to established procedures to ensure that the change does not create an adverse impact elsewhere in the operation. Process changes must be approved before implementation by a responsible person and approved changes must be communicated to appropriate personnel in a timely manner. The current standards for AATB, FACT, and the AABB provide for SOPs for process changes, although recordkeeping procedures are not specified. Current EBAA standards do not provide for SOPs for process changes. FDA therefore estimates that nearly all eye banks will need to prepare a major procedure for process changes, and will allocate an additional 1/2 hour of lab director time to document process changes.

FDA anticipates that the 23 percent of conventional tissue banks not following the AATB standards will need to prepare a major procedure related to process changes, and that nearly all tissue banks will increase related recordkeeping. The agency estimates that small conventional tissue banks will spend an additional 1/2 hour per month of lab director time to document process changes, and that large establishments would allocate an additional hour of lab director time per month for this activity. FDA anticipates that almost all hematopoietic stem/progenitor cell establishments that do not follow FACT or AABB standards will need to prepare a major procedure to address process changes. In addition, FDA estimates that 95 percent of all hematopoietic stem/progenitor cell establishments will also allocate an additional half hour of lab director time per month to document process changes. The associated costs per establishment are presented in table 4 of this document.

m. Section 1271.230—process validation. This final rule requires establishments to validate processes that cannot be verified through subsequent inspection and testing, and that the validation activities and results be documented. Current EBAA standards do not require process validation. Based on information provided by industry sources, FDA believes that some of the larger eye banks may already be performing the required process validation. Although current AATB, FACT, and AABB standards include provisions for process validation and related recordkeeping, industry experts indicate that additional validation work will be required at nearly all establishments under the CGTP final rule. FDA therefore estimates that 95 percent of all eye banks, conventional tissue banks, and all hematopoietic stem/progenitor cell establishments not following AABB or FACT voluntary standards, will prepare two major procedures related to process validation, and 95 percent of conventional tissue banks and hematopoietic stem/progenitor cell establishments will revise two major procedures. Further, FDA estimates that 95 percent of all establishments in each sector of the HCT/P industry will devote additional staff time to perform process validation. Details of these assumptions are provided in section 2.4.12 of the background papers (see footnote 1 of this document) by ERG and FDA.

In addition to the initial validation work, the CGTP final rule requires revalidation when changes to a validated process occur. The agency estimates that approximately 95 percent of eye banks, conventional tissue banks, and hematopoietic stem/progenitor cell establishments will need to allocate an additional 20 to 40 hours of laboratory staff time annually for procedure revalidation. Costs for these provisions of the CGTP rule are presented in table 4.

n. Section 1271.250—labeling controls. The CGTP rule requires establishments to establish and maintain written procedures for controlling the labeling of products. These procedures must ensure proper identification of products and include various checks and verifications. Each product must also be accompanied by a summary of donor eligibility information, if applicable.

According to consultants and industry contacts, labeling controls are usual and customary practice in all sectors of the HCT/P industry. FDA anticipates that only about 5 percent of eye banks, conventional tissue banks and hematopoietic stem/progenitor cell processing establishments will need to perform additional work to comply with the CGTP labeling controls. FDA estimates that such establishments will need to revise a major procedure for proper identification of products.

o. Section 1271.260—storage. The CGTP final rule requires that storage areas be controlled to prevent mixups, contamination, cross-contamination, and to prevent an HCT/P from being improperly made available for distribution. Temperature must be monitored and limits established, including expiration dating where appropriate. Each of the relevant HCT/P industry standards contains provisions regarding storage practices. Based on agency review of current industry standards, and conversations with experts about current practices at HCT/P establishments, FDA anticipates that virtually all establishments already comply with these provisions of the CGTP rule. These provisions are therefore expected to produce no new cost impact for eye banks, conventional tissue banks and hematopoietic stem/progenitor cell processing establishments.

p. Section 1271.265—receipt, predistribution shipment, and distribution. The CGTP final rule requires that procedures be established and maintained for receipt (e.g., determination of whether to accept, reject, or place the HCT/P in quarantine), predistribution shipment, and distribution of HCT/Ps. Documentation of each of the aforementioned activities, when performed, is also required. Packaging and shipping containers must be designed and constructed to protect the HCT/P from contamination, and appropriate shipping conditions must be established and maintained during transit. Procedures must also be established to determine whether products returned to an establishment are suitable to be returned to inventory. Agency review of current industry standards indicates that most provisions related to this area of quality control are included in each of the relevant industry standards.

The primary impact of the CGTP provisions for product receipt, predistribution shipment, and distribution, thus, involves procedures development for establishments that do not currently follow industry standards. FDA estimates that 5 percent of eye banks, conventional tissue banks, and hematopoietic stem/progenitor cell establishments will increase lab supervisor time to document the receipt of products.

The agency estimates that conventional tissue banks not following AATB standards will need to revise one major procedure for receiving products, revise one major procedure related to distribution of products, and prepare a minor procedure for return of products to inventory. FDA estimates that 95 percent of hematopoietic stem/progenitor cell establishments will write one major procedure addressing receiving activities. Establishments following FACT or AABB standards will also need to revise a major procedure for product distribution, while all other establishments will need to prepare a new major procedure for product distribution, as well as a minor procedure for the handling of products returned to inventory. Details of these assumptions are presented in section 2.4.15 of the background papers (see footnote 1 of this document) by ERG and FDA and the estimated costs per establishment for these activities are presented in table 4 of this document.

q. Section 1271.270—records. The CGTP rule requires that records be maintained for all steps required in this subpart and subpart C of this part. A records management system relating only to core CGTP requirements must be established and maintained. Records pertaining to a particular HCT/P must be maintained for at least 10 years after the date of administration, if known, or at least 10 years after the date of the HCT/P's distribution, disposition or expiration, whichever is latest. This final rule also requires that records be kept of any contracts or agreements. Although many components of the required recordkeeping system are addressed under individual provisions of the CGTP rule, there may be a few minor gaps in the records system of an establishment that would be addressed under this general provision. The agency therefore estimates that approximately 95 percent of all eye banks, conventional tissue banks, and hematopoietic stem/progenitor cell establishments that do not follow FACT or AABB standards, will write at least one minor procedure, and revise one major procedure related to recordkeeping.

The agency also estimates that additional lab director time will be allocated (an estimated 40 hours at small establishments and 80 hours at large establishments) to set up enhanced recordkeeping where a system is already in place. System enhancement will be performed at an estimated 95 percent of eye banks, 23 percent of conventional tissue banks and 95 percent of hematopoietic stem/progenitor cell establishments.

Various industry standards specify record retention, although the time periods vary somewhat. Of those establishments following industry standards, approximately 95 percent of eye banks and 75 percent to 80 percent of conventional tissue banks retain records for at least 10 years, and the remainder retain records for a minimum of 5 years. For these establishments, and the hematopoietic stem/progenitor cell establishments that do not currently follow industry standards, FDA estimates increased record retention costs based on the cost of storing an additional five boxes (2.4 cubic feet each) of records per year for 5 years. The estimated record retention costs should be viewed as maximum potential burdens since affected entities have the option to retain the required records in more cost-effective (e.g., electronic) formats and because some establishments already retain records for 10 years.

The retention standards of FACT and AABB for records related to products are different from those concerned with facility and equipment maintenance, and personnel education and training. All records related to hematopoietic stem/progenitor cell products must be retained indefinitely whereas records related to facility and equipment maintenance and personnel training must be retained for only 5 years.

FDA estimates that half of the records at hematopoietic stem/progenitor cell establishments following industry standards will need to be retained for an additional 5 years, and that the annual cost will be comparable to that of other small eye banks and conventional tissue banks. The agency also estimates that nearly all hematopoietic stem/progenitor cell establishments that are not following industry standards will need to increase record retention efforts. Almost all hematopoietic stem/progenitor cell establishments that do not follow industry standards are also expected to prepare at least one minor procedure and to revise a major procedure related to recordkeeping. The laboratory director at these establishments is expected to allocate 40 hours of additional time to improving the establishment's current recordkeeping system.

r. Section 1271.290—tracking. This final rule stipulates the steps needed to properly track a product from donor to consignee or final disposition and vice versa. The CGTP rule requires that establishments maintain a method for product tracking and that each product is assigned and labeled with a distinct identification code (identifier). If a new identifier is assigned during the manufacturing process, procedures must be in place for relating the new identifier to the old identifier. The establishment that manufactured the product must also keep track of the disposition of each product, so that the consignee can be easily identified. Establishments must also inform consignees in writing of the requirements of this section and of the established tracking method. In addition, labeling must include information designed to facilitate effective tracking from the donor to the recipient and from the recipient to the donor.

Product ''traceability'' is a familiar concept and common practice in the eye banking, conventional tissue and hematopoietic stem/progenitor cell processing industries. Eye banks following EBAA standards maintain records with information that permits tracing of product from the donor source to the patient recipient, working through the surgeon who performed the procedure. FDA anticipates that only 5 percent of eye banks will need to enhance current tracking systems, prepare one major procedure related to product tracking, spend additional staff time each month to identify and document consignee information, and allocate additional laboratory director time to inform the consignees who receive products and ensure the tracking requirements are met.

Conventional tissue banks following AATB standards are able to trace all products from donation source to product recipient. Conventional tissue establishments not following AATB requirements will need to revise a major procedure to address product tracking, and to allocate additional staff time each month to obtain and record information about product consignees. The FACT and AABB standards for product tracking in hematopoietic stem/progenitor cell establishments recommend that the establishment be able to trace products to final distribution or disposition, but do not specify that formal agreements be established with consignees to assure timely tracking of products. FDA therefore estimates that 95 percent of

hematopoietic stem/progenitor cell establishments will, on a one-time basis, allocate an additional 20 hours of laboratory supervisor time to inform consignees who will receive products of tracking systems and requirements. In addition, FDA estimates that 95 percent of hematopoietic stem/progenitor cell establishments that are not following FACT or AABB standards will need to revise a major procedure related to product tracking, and will need to allocate additional staff hours each month for consignee documentation. The estimated costs per establishment to perform these activities are presented in table 4 of this document.

s. Section 1271.320—complaint file. The CGTP final rule requires establishments to maintain procedures for the review, evaluation, and documentation of complaints relating to core CGTP requirements, and the investigation of complaints as appropriate. Establishments are required to review and evaluate complaints as soon as practical and to determine whether each complaint represents an event that must be reported to FDA. Documentation of the review and evaluation is required, even if no reporting is made. FDA finds that the AATB, FACT, and AABB standards explicitly address procedures for, or recordkeeping related to, complaints. Based on discussions with industry experts, the agency anticipates that nearly all establishments currently track, albeit informally, the complaints received from consignees and recipients. Establishments that must prepare new written procedures for review and handling of complaints would incur additional costs under these CGTP provisions. The agency estimates that the additional costs for establishments to maintain a complaint file would be negligible.

To fully comply with these provisions of the CGTP rule, FDA estimates that 95 percent of all eye banks will revise a minor procedure to include the required handling of complaints, and allocate some additional staff time each year to review complaints. FDA assumes that conventional tissue banks following AATB standards will already be performing the necessary activities, but the estimated 23 percent of establishments not following AATB standards will need to prepare a minor procedure for complaint handling, and allocate additional laboratory director time each year to review any complaints received.

Although the industry standards for hematopoietic stem/progenitor cell processing require that records be maintained of both donor and recipient complaints, the CGTP rule requires that establishments also have written procedures for complaint review. FDA therefore estimates that 95 percent of hematopoietic stem/progenitor cell establishments will write a minor procedure to handle complaints, and that 95 percent of all establishments that do not follow industry standards will also allocate additional time for yearly review and handling of complaints. Details of these assumptions are presented in section 2.4.18 of the background papers (see footnote 1 of this document) by FDA and ERG.

t. Section 1271.350—reporting. This final rule requires establishments to investigate adverse reaction reports and report to FDA any adverse reactions, involving a communicable disease, that are fatal, life-threatening, result in permanent impairment of the body, or necessitate medical or surgical intervention, including hospitalization. In addition, the final rule requires establishments to investigate all HCT/P deviations and report to FDA any deviation related to core CGTP requirements if the deviation occurs in the establishment's facility or in a facility that performs a manufacturing step under contract, agreement, or other arrangement with the establishment. In our economic analysis of the proposed CGTP rule, we assumed that these provisions would result in negligible new costs for affected entities. However, because these are new FDA reporting requirements, the agency believes that additional costs will be incurred by all eye banks, conventional tissue banks, and hematopoietic stem/progenitor cell establishments. The agency further estimates that a typical affected establishment will submit an average of six Form FDA 3500A (adverse reaction) reports and two Form FDA 3486 (HCT/P deviation) reports per year, requiring an additional 8 hours of laboratory director time. The associated costs are presented in table 4 of this document.

u. Section 1271.370—labeling. The CGTP rule requires that products be labeled clearly and accurately, with information including a description of the HCT/P along with its distinct identification code, the name and address of the manufacturer, a description of the product and the product expiration date. The storage temperature, appropriate warnings, and adequate instructions for use when related to the prevention of the introduction, transmission, or spread of communicable disease must also be provided on the label or on a package insert.

Industry consultants inform FDA that the required elements are typically present on the labels of products manufactured by eye banks, conventional tissue banks, and hematopoietic stem/progenitor cell establishments. Proper labeling is considered very important to these industries, to prevent the misuse of their products. FDA assumes, therefore, that establishments in the various sectors of the HCT/P industry are already compliant with these provisions of the CGTP final rule, and that the cost impact will be negligible.

v. Section 1271.400—inspections. FDA could conduct inspections of any facility subject to the CGTP final rule. FDA will typically interact primarily with one responsible person for each establishment, but other personnel may also be involved in the inspection. FDA could inspect facilities, equipment, processes, products, procedures, labeling, and records, and could review and copy any records required to be kept under this final rule. The agency estimates that all industry establishments, both domestic and foreign, will be subject to this provision of the CGTP final rule, and inspections will occur periodically. FDA estimates that up to 16 hours of laboratory technician time will be necessary, to accompany the FDA inspector through the facility and to support the inspector's information needs, and that up to 4 hours of laboratory director time will be needed for activities related to the inspection. This is expected to impose a cost of approximately $768 per establishment per inspection.

w. Section 1271.420—HCT/Ps offered for import. The CGTP final rule requires importers of HCT/Ps to notify the FDA district director having jurisdiction over the port of entry through which the HCT/P is imported or offered for import. The HCT/P must be held intact or transported under quarantine until it is inspected and released by FDA. There is currently very limited use of imported HCT/Ps that would trigger activities for compliance with this provision of the CGTP final rule. FDA therefore estimates the current cost for industry compliance with this requirement to be negligible.

x. Section 1271.440—orders of retention, recall, and cessation of manufacturing. Firms in the HCT/P industry may incur costs to comply with orders issued under this provision. There is little available data on which to base estimates of the future frequency and scope of HCT/P industry conditions and practices that would necessitate such actions on the part of FDA. The agency anticipates that orders issued under this provision of the CGTP final rule will be rare. FDA estimates that the

yearly costs to the HCT/P industry resulting from such orders will therefore be negligible.

3. Estimated Impact on Reproductive Tissue Establishments

As explained elsewhere in this preamble, establishments involved with reproductive tissue (e.g., ART establishments and semen banks) are subject only to the CGTP inspection and enforcement provisions of § 1271.400 as they apply to donor eligibility requirements under subpart C. The impact of these provisions is described in the following section and the estimated cost impact is presented in table 6 of this document.

TABLE 6.—ESTIMATED COST PER ESTABLISHMENT AND ESTIMATED PERCENTAGE OF REPRODUCTIVE TISSUE ESTABLISHMENTS AFFECTED BY THE CGTP FINAL RULE

21 CFR Section	Title	ART Establishments	Semen Banks
1271.400	Inspections	$768 (100%)	$768 (100%)

a. Section 1271.400—inspections. FDA could conduct inspections of any facility subject to subpart F. This provision affects reproductive tissue establishments only insofar as it applies to the donor eligibility requirements under subpart C, and not to CGTPs generally. FDA will typically interact primarily with one responsible person for each establishment, but other personnel may also be involved in the inspection. FDA could inspect the donor eligibility related procedures and records of reproductive tissue establishments, and could review and copy any records required to be kept under this final rule.

The agency estimates that all ART and semen bank establishments, whether domestic or foreign, will be subject to this provision of the CGTP final rule, and inspections will occur periodically. FDA estimates that up to 16 hours of laboratory technician time will be necessary, to accompany the FDA inspector through the establishment and to support the inspector's information needs, and that up to 4 hours of laboratory director time will be needed for activities related to the inspection. This is expected to impose a cost of approximately $768 per establishment per inspection. This is the only provision of the CGTP final rule that applies to establishments involved with reproductive tissues.

4. Summary of Estimated One-Time, Annual, and Annualized Cost Impacts

The costs for each section of the CGTP final rule are computed as the product of the estimated number of affected establishments (table 3 of this document), the estimated compliance cost per establishment, and the estimated percentage of establishments not currently following CGTPs (table 4 of this document), and are presented by HCT/P industry sector in tables 7 through 11 of this document. The total one-time and annual compliance costs, summed over all provisions of the CGTP rule, are also presented by HCT/P industry sector in these tables. The aggregate one-time and annual compliance costs for all sectors of the HCT/P industry are summarized in table 12 of this document. The total annualized cost estimates presented in tables 7 through 12 of this document include both the estimated annual and one-time costs, such as are incurred to prepare new procedures, and are annualized over 10 years using both 7 percent and 3 percent discount rates.

TABLE 7.—AGGREGATE COMPLIANCE COSTS FOR EYE BANKS

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.150	CGTP Requirements	$0	$0	$0	$0
1271.155	Exemptions & Alternatives	$0	$0	$0	$0
1271.160	Quality Program	$159,038	$569,031	$591,674	$587,675
1271.170	Personnel	$0	$0	$0	$0
1271.180	Procedures	$0	$61,104	$61,104	$61,104
1271.190	Facilities	2,328	$0	$331	$273
1271.195	Environmental Control & Monitoring	$0	$28,550	$28,850	$28,850
1271.200	Equipment	$0	$138,248	$138,248	$138,248
1271.210	Supplies & Reagents	$16,613	$22,150	$24,515	$24,098
1271.215	Recovery	$0	$0	$0	$0
1271.220	Processing and Process Controls	$48,374	$0	$6,887	$5,671
1271.225	Process Changes	$96,748	$58,049	$71,824	$69,391
1271.230	Process Validation	$409,906	$108,205	$166,566	$156,258
1271.250	Labeling Controls	$2,456	$0	$362	$298

TABLE 7.—AGGREGATE COMPLIANCE COSTS FOR EYE BANKS—Continued

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.260	Storage	$0	$0	$0	$0
1271.265	Receipt, Predistribution Shipment & Distribution	$0	$182,990	$182,990	$182,990
1271.270	Records	$479,603	$121	$68,405	$56,345
1271.290	Tracking	$15,276	$11,578	$13,753	$13,368
1271.320	Complaint File	$16,613	$77,398	$79,764	$79,364
1271.350	Reporting	$0	$81,472	$81,472	$81,472
1271.370	Labeling	$0	$0	$0	$0
1271.400	Inspections	$0	$102,912	$102,912	$102,912
1271.420	HCT/Ps Offered for Import	$0	$0	$0	$0
1271.440	Orders of Retention, Recall, Destruction and Cessation of Manufacturing	$0	$0	$0	$0
Total	All Sections	$1,247,044	$1,442,108	$1,619,659	$1,588,300

[1] Over 10 years at 7 percent interest.
[2] Over 10 years at 3 percent interest.

TABLE 8.—AGGREGATE COMPLIANCE COSTS FOR CONVENTIONAL TISSUE ESTABLISHMENTS

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.150	CGTP Requirements	$0	$0	$0	$0
1271.155	Exemptions & Alternatives	$0	$0	$0	$0
1271.160	Quality Program	$127,960	$213,246	$231,464	$228,247
1271.170	Personnel	$594,081	$101,444	$186,028	$171,088
1271.180	Procedures	$0	$348,202	$348,202	$348,202
1271.190	Facilities	$14,838	$0	$2,113	$1,739
1271.195	Environmental Control & Monitoring	$14,838	$8,124	$10,237	$9,863
1271.200	Equipment	$137,313	$101,411	$120,961	$117,508
1271.210	Supplies & Reagents	$29,676	$8,124	$12,349	$11,603
1271.215	Recovery	$0	$0	$0	$0
1271.220	Processing and Process Controls	$20,516	$0	$2,921	$2,405
1271.225	Process Changes	$41,033	$87,940	$93,782	$92,750
1271.230	Process Validation	$437,574	$268,090	$330,391	$319,387
1271.250	Labeling Controls	$4,460	$0	$635	$523
1271.260	Storage	$0	$0	$0	$0
1271.265	Receipt, Predistribution Shipment & Distribution	$55,871	$237,058	$245,012	$243,607
1271.270	Records	$287,965	$687	$41,687	$34,446
1271.290	Tracking	$78,550	$161,361	$172,544	$170,569
1271.320	Complaint File	$14,837	$28,388	$30,500	$30,127
1271.350	Reporting	$0	$100,928	$100,928	$100,928

TABLE 8.—AGGREGATE COMPLIANCE COSTS FOR CONVENTIONAL TISSUE ESTABLISHMENTS—Continued

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.370	Labeling	$0	$0	$0	$0
1271.400	Inspections	$0	$127,488	$127,488	$127,488
1271.420	HCT/Ps Offered for Import	$0	$0	$0	$0
1271.440	Orders of Retention, Recall, Destruction and Cessation of Manufacturing	$0	$0	$0	$0
Total	All Sections	$1,859,510	$1,792,489	$2,057,241	$2,010,480

[a.] Over 10 years at 7 percent interest
[b.] Over 10 years at 3 percent interest

TABLE 9.—AGGREGATE COMPLIANCE COSTS FOR HEMATOPOIETIC STEM/PROGENITOR CELL ESTABLISHMENTS

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[a]	Total Annualized Costs[b]
1271.150	CGTP Requirements	$0	$0	$0	$0
1271.155	Exemptions & Alternatives	$0	$0	$0	$0
1271.160	Quality Program	$208,354	$457,200	$486,865	$481,625
1271.170	Personnel	$739,100	$117,610	$222,841	$204,255
1271.180	Procedures	$0	$433,200	$433,200	$433,200
1271.190	Facilities	$90,784	$665,000	$677,926	$675,643
1271.195	Environmental Control & Monitoring	$90,784	$205,458	$218,383	$216,100
1271.200	Equipment	$450,621	$465,548	$529,706	$518,374
1271.210	Supplies & Reagents	$135,185	$8,265	$27,512	$24,113
1271.215	Recovery	$0	$0	$0	$0
1271.220	Processing and Process Controls	$198,550	$0	$28,269	$23,276
1271.225	Process Changes	$36,100	$119,130	$124,270	$123,362
1271.230	Process Validation	$678,775	$297,825	$394,467	$372,398
1271.250	Labeling Controls	$5,225	$0	$744	$613
1271.260	Storage	$0	$0	$0	$0
1271.265	Receipt, Predistribution Shipment & Distribution	$482,861	$28,080	$96,829	$84,686
1271.270	Records	$178,956	$2,880	$28,359	$23,859
1271.290	Tracking	$415,150	$164,160	$223,268	$212,828
1271.320	Complaint File	$90,784	$158,840	$171,766	$169,483
1271.350	Reporting	$0	$167,200	$167,200	$167,200
1271.370	Labeling	$0	$0	$0	$0
1271.400	Inspections	$0	$211,200	$211,200	$211,200
1271.420	HCT/Ps Offered for Import	$0	$0	$0	$0
1271.440	Orders of Retention, Recall, Destruction and Cessation of Manufacturing	$0	$0	$0	$0
Total	All Sections	$3,801,230	$3,501,595	$4,042,805	$3,947,215

[1] Over 10 years at 7 percent interest.
[2] Over 10 years at 3 percent interest.

TABLE 10.—AGGREGATE COMPLIANCE COSTS FOR ART ESTABLISHMENTS

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.400	Inspections	$0	$307,200	$307,200	$307,200
Total	All Sections	$0	$307,200	$307,200	$307,200

[1] Over 10 years at 7 percent interest.
[2] Over 10 years at 3 percent interest.

TABLE 11.—AGGREGATE COMPLIANCE COSTS FOR SEMEN BANKS

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.400	Inspections	$0	$84,480	$84,480	$84,480
Total	All Sections	$0	$84,480	$84,480	$84,480

[1] Over 10 years at 7 percent interest.
[2] Over 10 years at 3 percent interest.

TABLE 12.—AGGREGATE COMPLIANCE COSTS FOR ALL HCT/P INDUSTRY SECTORS

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.150	CGTP Requirements	$0	$0	$0	$0
1271.155	Exemptions & Alternatives	$0	$0	$0	$0
1271.160	Quality Program	$495,351	$1,239,477	$1,310,003	$1,297,547
1271.170	Personnel	$1,333,181	$219,054	$408,869	$375,343
1271.180	Procedures	$0	$842,506	$842,506	$842,506
1271.190	Facilities	$107,950	$665,000	$680,370	$677,655
1271.195	Environmental Control & Monitoring	$105,622	$242,432	$257,470	$254,814
1271.200	Equipment	$587,933	$705,206	$788,914	$774,130
1271.210	Supplies & Reagents	$181,473	$38,539	$64,377	$59,813
1271.215	Recovery	$0	$0	$0	$0
1271.220	Processing and Process Controls	$267,440	$0	$38,077	$31,352
1271.225	Process Changes	$173,881	$265,118	$289,875	$285,503
1271.230	Process Validation	$1,526,255	$674,120	$891,424	$853,044
1271.250	Labeling Controls	$12,231	$0	$1,741	$1,434
1271.260	Storage	$0	$0	$0	$0
1271.265	Receipt, Predistribution Shipment & Distribution	$538,732	$448,128	$524,831	$511,284
1271.270	Records	$946,524	$3,688	$138,452	$114,649
1271.290	Tracking	$508,976	$337,098	$409,565	$396,766
1271.320	Complaint File	$122,235	$264,626	$282,029	$278,956
1271.350	Reporting	$0	$349,600	$349,600	$349,600
1271.370	Labeling	$0	$0	$0	$0
1271.400	Inspections	$0	$833,280	$833,280	$833,280
1271.420	HCT/Ps Offered for Import	$0	$0	$0	$0

TABLE 12.—AGGREGATE COMPLIANCE COSTS FOR ALL HCT/P INDUSTRY SECTORS—Continued

21 CFR Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs[1]	Total Annualized Costs[2]
1271.440	Orders of Retention, Recall, Destruction and Cessation of Manufacturing	$0	$0	$0	$0
Total	All Sections	$6,907,784	$7,127,872	$8,111,384	$7,937,674

[1] Over 10 years at 7 percent interest.
[2] Over 10 years at 3 percent interest.

As shown in table 7 of this document, the total one-time costs for the eye banking industry are estimated to be $1.25 million, and annual costs are estimated at $1.44 million. These figures generate a total annualized cost estimate of $1.59 million to $1.62 million. For the conventional tissue industry (table 8 of this document), aggregate one-time costs and annual costs are estimated at $1.86 million and $1.79 million, respectively. These figures correspond to an estimated annualized cost of $2.01 million to $2.06 million. The hematopoietic stem/progenitor cell industry (table 9 of this document) is estimated to incur a one-time cost of $3.8 million and annual costs of $3.5 million, yielding an annualized cost estimate of $3.95 million to $4.04 million. ART establishments and semen banks are expected to incur no one-time costs under the CGTP final rule because they are subject only to the inspection and enforcement provisions as they relate to donor eligibility requirements under subpart C. The total annual and annualized costs for ART establishments and semen banks are estimated to be $0.31 million and $0.08 million, respectively. These cost estimates are presented in tables 10 and 11 of this document.

Table 12 of this document summarizes the total estimated cost impacts for all HCT/P industry sectors. FDA estimates the aggregate one-time compliance costs of the CGTP final rule to be $6.9 million. Annual costs, aggregated across all sectors of the HCT/P industry, are estimated to be $7.13 million. These estimates correspond to a total annualized cost estimate of $7.94 million to $8.1 million for the CGTP final rule applied to all major sectors of the HCT/P industry.

C. Estimated Benefits of the CGTP Final Rule

The purpose of the CGTP final rule is to prevent the introduction, transmission, or spread of communicable disease through the use of HCT/Ps. Although voluntary industry standards exist for most of the affected products, FDA finds that public safety cannot be assured or effectively protected through reliance on these informal mechanisms. The existing industry standards also vary to some extent in their comprehensiveness, and there are variations in the extent to which firms in the affected industry sectors follow these voluntary standards.

For example, most industry consultants providing input for this analysis agreed that quality standards, such as those in the CGTP final rule, and similar standards recommended by industry, could substantially reduce the risk of HCT/P product contamination by communicable disease agents. However, most of these experts also agreed that, because additional costs are associated with maintaining higher quality standards, and because there is no explicit patient demand for higher quality standards to prevent contamination risks, some establishments are not currently following adequate quality control procedures. A regulatory requirement for quality systems and recordkeeping would provide the incentives needed to bring marginal establishments to a more uniform and appropriately high standard of quality in HCT/P processing.

The primary beneficiaries of the CGTP final rule are the patients who receive HCT/Ps. Benefits to patients result from improved outcomes due to reduced risks of communicable disease transmission. Society as a whole will benefit from implementation of CGTPs due to improved safety of the supply of HCT/Ps, and reductions in health care and other costs associated with treating the complications arising from the use of contaminated tissue products. The discussion that follows considers some of the potential benefits of CGTPs based on a survey of the clinical literature.

Recent clinical literature indicates that each type of HCT/P affected by the CGTP final rule has documented communicable disease transmission risk that may be the result of contamination or other problems resulting from processing, or other steps in manufacturing. Although the limited number of adverse events reported in the clinical literature suggests a relatively low risk of communicable disease transmission associated with HCT/Ps, it is important to note that this evidence is generally based on analysis of a limited number of voluntarily reported incidents. The reported HCT/P problems provide a basis for assessing the magnitude of the potential benefit from further reducing the incidence of events that contribute to or increase the risk of communicable disease transmission. In some cases involving eye tissue, conventional tissue, or hematopoietic stem/progenitor cell products, HCT/P problems have required medical intervention to treat infection, or to replace an implanted HCT/P. In some clinical applications, HCT/P related problems have increased the risk of patient morbidity or mortality. In general, FDA anticipates that the risk of communicable disease transmission will decline, and patient outcomes will improve, as a result of industry compliance with the provisions of the CGTP final rule.

The sections that follow describe specific product-related problems associated with communicable disease transmission that are at least partly attributable to a lack of uniform and enforceable standards in HCT/P manufacturing. The costs of correcting these problems are considered, to gauge the potential magnitude of the benefits associated with improvements in manufacturing processes brought about through implementation of CGTPs. The discussion is organized by type of HCT/P.

1. Eye Tissue

Primary corneal graft failure is a key adverse outcome of concern following corneal tissue transplant. Such failures result in additional graft attempts, and each attempt increases the risk of communicable disease transmission by exposing the recipient to another HCT/P, and another surgical procedure. Although primary corneal graft failure is relatively uncommon, its occurrence has been attributed to several factors related

to tissue collection, processing, and product distribution. These factors include donor characteristics such as age (Ref. 5), donor infectivity (e.g., with Herpes Simplex Virus and CJD) (Refs. 8 and 31), length of product storage, type of storage medium, and shipping distance from the eye bank to the recipient site. In an analysis of factors contributing to primary corneal graft failure, Wilhelmus et al. (Ref. 5) found that ''the duration of donor corneal preservation may have a significant effect on endothelial vitality,'' citing studies that demonstrate endothelial cell loss in chondroitin-supplemented storage media after 7 to 10 days of storage. The authors suggest that, even with modern eye bank screening and preservation procedures, a donor corneal storage time greater than 1 week increases the risk of primary corneal graft failure by more than two-fold.

Wilhelmus et al. include in their analysis a summary of selected findings of studies published between 1971 and 1994 that report the incidence of primary graft failure for corneal transplants using 4 degrees Celsius preservation, and a variety of preservation methods. The rates of primary graft failure reported ranged from 0.9 percent to 3.1 percent, and a combined rate of 2.1 percent was estimated across all preservation methods. In their analysis of factors associated with corneal graft failures reported to the EBAA for 1991 to 1993, the findings of Wilhelmus et al. illustrate the importance of verification of quality and documentation of the receipt of supplies and reagents used in HCT/P processing. The authors found that 86 cases (approximately 59 percent of all cases studied) of primary corneal graft failure shared preservation media from the same lots. These findings underline the importance of the CGTP requirement for verification of quality and documentation of receipt for each particular lot of processing media used in the manufacture of uniquely labeled and traceable products.

Primary corneal graft failure typically requires repeat surgery to replace the failed graft. The Agency for Healthcare Research and Quality (AHRQ), reports 598 total discharges for Principal Procedure 13, Corneal transplant, with a mean hospital length of stay (LOS) of 3.5 days and a mean hospital charge of $14,233 in 2000 (Ref.7). The estimated rate of primary graft failure, which may result from one or more aspects of cornea collection, processing, or distribution, ranges from 0.1 percent (based on the number of cases voluntarily reported to EBAA for the period 1991–1993, and again in 2001) to as much as 2.1 percent (combined failure rate reported in the literature, across the range of preservation media currently used in eye tissue processing, cited in Wilhelmus et al.). Based on 45,897 corneal transplants reported by the EBAA in 1999, the estimated number of cases of primary graft failure may range from 46 cases [0.001 x 45,897] to 413 cases [0.009 x 45,897] per year. The lowest estimate of the incidence of primary corneal graft failure reported by Wilhelmus et al. (0.9 percent) was used in this calculation to produce a conservative estimate of the number of cases, and in response to public comments on the proposed CGTP rule. The total cost of replacement of a failed corneal graft is estimated to include $654 of physician services (Ref.8), including an office visit to diagnose the graft failure before hospitalization, and initial and followup physician visits during patient hospitalization for the repeated corneal transplant. It also includes one followup physician office visit to assess the outcome of the second transplant. The patient is estimated to further incur at least 1 week of time lost from work for doctor visits, hospitalization, and recovery of visual function after surgery. The cost of this patient time loss is estimated at $957.20, based on a 40-hour work week and U.S. average employer costs for employee compensation of $23.93 (Ref. 32). Thus, the current annual cost impact of primary corneal graft failure may range from $728,833 (46 x ($14,233 + $654 + $957.20)) to $6,543,655 (413 x ($14,233 + $654 + $957.20)).

The risk, incidence, and cost of treating primary corneal graft failure will be reduced through the implementation of CGTPs, due to provisions requiring the validation of processing methods and process quality controls, the verification of supplies and reagents, and improved documentation. The total annualized cost to eye banks of implementing the CGTP final rule is estimated to be $1.61 million to $1.65 million, and the total cost of repeat surgery, hospitalization, physician's services and work loss associated with primary corneal graft failure is estimated to be $15,844.20 per occurrence ($14,233 + $654 + $957.20). Based on these estimates, if implementation of the CGTP final rule were to result in approximately 104 fewer cases ($1.65 million / $15,844 per case) of primary corneal graft failure per year, the benefits realized (in the form of avoided health care costs and income loss due to time away from work) would exceed the total annualized cost to eye banks, thereby making the rule cost effective for this sector of the HCT/P industry.

A reduction of 104 cases represents a 25 percent reduction (104 fewer cases / 413 total cases) in the risk of corneal graft failure (from 0.9 percent to 0.675 percent) based on the lowest rate reported by Wilhelmus et al. Due to uncertainty with respect to the actual risk of primary corneal graft failure, and the degree to which CGTPs would reduce this already uncertain risk, FDA is not able to determine whether or not implementation of this final rule would generate this level of risk reduction. No attempt was made to estimate the benefits of any potential reduction in the risk of intraocular infection (another HCT/P-related problem associated with eye tissue) resulting from implementation of CGTPs due to a lack of data.

2. Conventional Tissue

Conventional tissue refers to a wide range of HCT/Ps including pericardium, dura mater, heart valves, skin allograft, bone allograft, fascia, tendons, and ligaments. FDA's survey of the clinical literature indicates that bone, skin and heart valve allografts each present a different potential for communicable disease transmission risk and graft failure, and thus different levels of potential benefits from improved processing procedures and quality assurance steps in HCT/P manufacture. The discussion that follows considers these three distinct conventional tissue products and thus areas of potential benefit.

a. *Bone allograft.* An analysis of the incidence, nature, and treatment of infection associated with bone allograft by Lord et al. (Ref.9), demonstrates the importance of quality standards and process requirements to prevent tissue contamination. Of the 283 patients in their analysis who had received a massive allograft of bone, infection developed in 33 cases (11.7 percent). The final outcome for those 33 patients was poor compared to the 250 uninfected patients. About 82 percent (27 of the 33 patients) of the infected allografts were considered failures of treatment because amputation or resection of the graft was required to control the infection. Potential sources of contamination cited in the study include donor infection or contamination introduced during processing (estimated to occur in as many as 7 percent of the infected grafts), highlighting the critical need for HCT/Ps that are free from contamination by communicable disease agents. Other factors cited include duration of the

operation, loss of blood, injury to soft tissue, and skin sloughing during the operation.

The importance of process validation is also implied by Hardin (Ref.10) in a review of banked bone allograft processes. In describing methods for sterilization, Hardin identifies ethylene oxide as one of the chemicals used, but indicates that its effectiveness may nonetheless be questionable, because of reports of graft failures in which residues of ethylene oxide have been implicated, and some experimental evidence indicating toxicity of ethylene oxide in human tissues.

Based on an average rate of 0.057 for bone allograft failure due to contamination (based on an estimated allograft infection rate of 0.07 x an estimated 0.82 failure rate for infected bone allograft), and the conservative assumption that all graft failures would be treatable through repeat surgery to replace the bone allograft, the associated healthcare costs could be on the order of $60 million per year ($59,679,928 = 0.057 x 44,000 x ($22,497 + $1,133)). This figure is based on a national level estimate of 44,000 bone allografts per year (Ref.11), and a mean hospital charge of $22,497 for Principle Procedure 142, Partial excision of bone (Ref. 28). Physician costs per hospitalization are estimated to be $1,133, based on submitted charges per person served in the Orthopedic Surgery Physician Specialty category (Ref. 8).

The reported average length of hospital stay for bone surgery is approximately 6.3 days (Ref. 28). The estimated cost of patient time lost assumes that repeat surgery would require at least 1 week of time away from work, at an estimated value of $957.20, based on a 40-hour work week and average hourly compensation of $23.93 (Ref.32). This yields an estimated total patient time cost of $2,400,658 (0.057 x 44,000 x $9357.20). Thus, the total annual cost of bone allograft failure due to contamination is estimated to be approximately $62 million ($62,080,586 = $59,679,928 + $2,400,658).

If bone allograft failures result in amputation, the direct and indirect costs would be significantly higher. For example, the direct cost per hospitalization for lower extremity amputation is estimated to be $30,820 based on AHRQ Healthcare Cost and Utilization Project (HCUP) data (Ref. 23). Moreover, permanent disability following amputation imposes extremely high costs on the patient, the patient's family, and on society as a whole. The AHRQ HCUP data also report 5,200 in-hospital deaths and a 4.5 percent death rate associated with these amputation procedures.

FDA is uncertain about the extent to which the estimated cost impact will be reduced through implementation of the CGTP final rule for two reasons. First, many graft failures result from transplantation procedures and other factors not related to bone allograft manufacture, or from a combination of factors. Second, some establishments may have already developed new bone processing methods that may greatly reduce infection risk. If as much as 90 percent of the estimated risk is actually attributable to other factors, or has already been addressed through better manufacturing processes, the benefit from CGTPs applied to the remainder of bone tissue processes and establishments would be on the order of $6.2 million ($62,080,586 x 0.10) per year. The total annualized cost of the CGTP final rule for all conventional tissue banks is estimated to be $2.03 million to 2.07 million, and the estimated total cost of treatment for infected bone allograft, including hospitalization, physician's office visits and work loss is $24,587.20 per occurrence. If implementation of the CGTP final rule resulted approximately 84 fewer cases of infected bone allograft requiring repeat surgery ($2,073,547 / $24,587.2 = 84.3), the benefits of CGTPs would exceed the estimated total annualized costs for all conventional tissue banks. This reduction in the number of cases of bone allograft infection corresponds to a 3.3 percent reduction (84.3 fewer cases / 2,525.6 potential cases) in risk based on the information used as the basis for this analysis.

b. *Skin allograft.* Skin allografts represent another type of HCT/P that is critically dependent on processing and quality controls to prevent the manufacture, distribution and/or use of contaminated products. The clinical literature reports cases of cytomegalovirus (CMV) transmission due to skin donor infection (Ref.12), and HIV contamination from infected donor skin tissue and subsequent tissue processing (Ref.13). CMV infections are usually not life-threatening in healthy individuals, but present grave risks to the types of patients who typically require skin grafts. In general, patients who have suffered severe burns and require skin grafts are immunosuppressed as a result of their injuries and are therefore susceptible to potentially life-threatening CMV infections. These include pneumonitis, retinitis, gastroenteritis, hepatitis, and neurological complications (Ref. 12). Contamination of skin allograft can also significantly affect burn patient survival. Because the clinical literature does not provide summary estimates of the risk of contamination associated with skin allograft, the agency is unable to quantify the level of associated risk. Although implementation of the CGTP final rule is expected to reduce the risk of contaminated skin allograft, and thereby improve burn patient outcomes, FDA could not quantify this source of expected patient benefits due to a lack of necessary information.

c. *Heart Valve Allografts.* Heart valve allografts, another of the many types of conventional tissue products, provides another compelling case for HCT/P production process validation and quality control. Human heart valve contaminants not effectively removed in tissue processing have resulted in serious infections that, at a minimum, require valve replacement and may also result in patient death. Sources of contamination of a heart valve allograft include the donor, the environment during harvesting and processing, and the operating room during implantation. Microbial contamination of human heart valves is common at tissue harvesting, with reports of over 50 percent contamination among valves retrieved in open mortuary areas. According to a study by Kuehnert et al. (Ref.14) common contaminants found before disinfection consist of gastrointestinal and skin flora (including coliforms), viridans group streptococci, *Staphylococcus aureus*, *S. epidermidis*, and *Bacillus* species. In general, bacterial contamination can be effectively removed through standard disinfection procedures used in most accredited conventional tissue banks. However, tissue that remains contaminated with these pathogens, particularly *Staphylococcus* and *Streptococcus* species, can cause early onset allograft valve endocarditis. In contrast to bacterial contamination, reported rates of fungal contamination of heart valve allograft are relatively low. However, Kuehnert et al. report that rates vary widely (1.7 percent to 28.0 percent), and that the inclusion of anti-fungal drugs in tissue disinfection regimens is not effective in eradicating fungal contamination.

Fungal endocarditis is a rare but potentially fatal complication of allograft heart valve replacement. According to Kuehnert et al., the incidence of fungal endocarditis following surgery for heart valve replacement with allograft is estimated to range from 0.3 percent to 1.4 percent (midpoint estimate of 0.85 percent). In one reported case, the infected patient needed subsequent surgery to replace

the valve and required treatment with intravenous amphotericin B for the following 8 weeks. In many cases, treatment is not successful and death results. In one review, cited by Kuehnert et al., over 40 percent of patients who had acquired fungal endocarditis after heart valve allograft implantation died within 2 weeks of diagnosis.

In their study, Kuehnert et al. describe the process controls used by AATB-affiliated establishments including the establishment, validation and documentation of decontamination protocols. Because these regimens have not been found effective against fungal contamination, AATB-affiliated establishments routinely discard tissue with documented fungal contamination. However, according to Kuehnert et al., the supplier of over 85 percent of all heart valve allografts (approximately 41,000 since 1984) does not follow AATB standards, but instead follows a decontamination protocol that is reported to be proprietary. This protocol apparently includes efforts to disinfect rather than discard tissue with fungal contamination. However, efforts to eradicate fungal contamination identified in processing can be unsuccessful, and in this case, a false-negative culture following processing results in tissue being distributed for use in patients.

The CGTP final rule requires that all establishments use validated procedures and that HCT/Ps meet all release criteria before they are made available for distribution. Based on the rates of infection and mortality risk reported by Kuehnert et al., and an estimated 5,000 to 6,000 human heart valve allografts per year (these figures were reported to the agency by the largest supplier of this type of HCT/P in their comment on the proposed rule), there may be an estimated 43 (0.0085 x 5,000) to 51 (0.0085 x 6,000) cases of fungal endocarditis each year. These cases of fungal endocarditis may further cause an estimated 17 (0.0085 x 0.40 x 5000) to 20 patient deaths per year (0.0085 x 0.40 x 6,000). Fungal endocarditis may result from a variety of peri- or post-operative factors including infection of the valve allograft itself. While highly uncertain, one comment suggested that as many as one-third of all cases of fungal endocarditis may be caused by contaminated valve allografts. Based on this information, FDA expects that there may be as many as 14 to 17 cases of heart valve contamination causing fungal endocarditis along with 5 to 7 patient deaths each year. Changes in processing procedures based on the CGTP requirements will help to avoid cases of fungal endocarditis and, perhaps, some of the resulting deaths. Substantial health care cost savings will also be achieved through improved processing controls and avoided adverse events due to implementation of the CGTP final rule.

AHRQ reports 82,874 total hospital discharges for Principle Procedure 43, Heart Valve Procedures in 2000 with a mean LOS of 11.1 days and mean hospital charges of $78,494 (Ref. 24). The AHRQ also reports 4,986 in-hospital deaths (and a 6.0 percent death rate) associated with these procedures. If patients undergoing this procedure were to lose 2 weeks of time away from work, the value of this work loss, based on a 40-hour work week and an average hourly compensation of $ 23.93 (Ref. 32), would be $1,914 per case. Based on reported average charges of $78,494 per hospitalization for implantation of a heart valve allograft (Ref. 24), estimated physician charges of $6,796 per case, including repeat surgery and patient care during the average 11.1-day hospital stay, and 2 weeks of patient work loss, the total cost of treating cases of heart valve contamination causing fungal endocarditis would be between $1,220,862 (14 x ($78,494 + $6,796 + $1,914.4)) and $1,482,475 (17 x ($78,494 + $6,796 + $1,914.4)). These estimates should be viewed as conservative because they reflect only the costs associated with contaminated heart valve allografts causing fungal endocarditis, and do not consider the costs associated with the more common bacteria-induced early onset allograft valve endocarditis. No estimate of the potential benefit of CGTPs in reducing the cost of treating early onset allograft valve endocarditis was generated due to a lack of necessary information.

The total annualized costs of the CGTP final rule for conventional tissue banks are estimated to be $2.03 million to $2.07 million. The total costs associated with infected bone allografts and contaminated heart valve allografts causing fungal endocarditis are estimated to be between $61.3 million ($60.1 million + $1.2 million) and $61.6 million ($60.1 million + $1.5 million). If implementation of the CGTP final rule were to reduce these estimated costs by 3.3 percent, the estimated annual cost savings, or benefit, would exceed the estimated compliance costs. Thus, a 3.3 percent reduction in the cost associated with only two HCT/P-related problems would make the CGTP final rule cost effective for the conventional tissue industry.

3. Hematopoietic Stem/Progenitor Cells

Promising outcomes from use of peripheral blood stem/progenitor cells (PBSC) and cord blood-derived stem/progenitor cells (CBSC) in lieu of bone marrow have resulted in increased collection and use of these products in hematopoietic stem/progenitor cell transplants. For example, recent studies have reported the use of PBSC (rather than bone marrow) in 54 percent (Ref. 15) and 62 percent of cases, respectively (Ref. 16). However, studies of hematopoietic stem/progenitor cell products indicate that products manufactured by this industry may become contaminated during collection and processing. Moreover, the therapy-induced immunosuppression of the oncology patients who receive these products places them at particularly high risk for serious infection and subsequent mortality. Manufacturing methods conforming to CGTP are necessary to prevent this threat to the safety and effectiveness of hematopoietic stem/progenitor cell therapies. For example, investigations of PBSC have reported that the large quantity of blood that must be processed to obtain adequate numbers of hematopoietic stem/progenitor cells resulted in large volumes of cryopreserved cells received by patients. This process posed the risk of increased toxicity, because of the amount of dimethyl sulfoxide used for cryopreservation (Ref. 20).

Another quality concern with PBSC involves the maintenance of the sterile integrity of the apheresis catheter and component throughout the period of leukapheresis, cryopreservation, thawing, and transfusion (Espinosa et al., 1996) (Ref. 17). Webb et al. (Ref. 18) reported a 2.41 percent rate of bacterial contamination in PBSC products, and a 13.7 percent rate of infection of patients receiving contaminated products.

Although bacteremia-induced fever and other clinical sequelae are generally considered reversible, infections present more serious risks for hematopoietic stem/progenitor cell recipients than for the overall population. Survival rates for hematopoietic stem/progenitor cell transplantation are significantly reduced for patients who become critically ill. In a study of survival rates among hematopoietic stem/progenitor cell recipients admitted to an intensive care unit, Price et al. (Ref. 16) found that patients with probable infection had a significantly higher death rate (57 percent) compared to patients with no probable infection (13 percent). Multiple regression analyses by Price et al., controlling for other risk factors such as patient intubation, type of transplant, source of hematopoietic stem/progenitor cells, human leukocyte antigen compatibility, type of

malignancy and patient age, also found infection to be a significant predictor of mortality.

Based on reported blood collection and transfusion statistics (Ref. 25), a total of 32,291 units of PBSCs were collected, and 18,123 units transfused, in the United States in 1997 (the use of PBSCs has been increasing steadily since that time). Thus, an estimated 60 patients per year (18,123 PBSC transfusions x 0.024 x 0.137) could suffer infection following receipt of contaminated PBSC, based on the reported rates of 2.4 percent of patients receiving contaminated PBSC, 13.7 percent of those patients subsequently developing infection (Ref. 15), and 18,123 hematopoietic stem/progenitor cell transplants performed in 1997. Costs of treating patients who become infected after receiving contaminated hematopoietic stem/progenitor cell products are estimated based on 8,985 AHRQ-reported total discharges for Principle Procedure 3, Bacterial Infection, Unspecified Site, with average hospital charges of $21,221 per 6.9-day patient stay (Ref. 26). Estimated total health care costs also include physician costs of $918 assuming one initial in-hospital visit, and daily followup visits during the patient stay (Ref. 8). Patient income loss is valued at $1,914 based on estimated hourly compensation of $23.93 (Ref. 32) and an estimated 2 weeks away from work. Thus, the total annual cost impact of infection following transplant of contaminated PBSC products is estimated to be $1,443,180 (60 x ($21,221 + $918 + $1,914)).

In addition to health care and time away from work costs, reducing the risk of contaminated PBSC products could result in avoiding 26 excess hematopoietic stem/progenitor cell patient deaths per year, due to infection. This number reflects the excess mortality risk reported for hematopoietic stem/progenitor cell recipients with infection versus those without infection. It is based on the following: (18,123 transplant procedures per year) x (2.41 percent PBSC patients receiving contaminated product) x (13.7 percent patients receiving contaminated product develop infection) x (44 percent excess mortality risk for hematopoietic stem/progenitor cell recipients with a probable infection). This estimate suggests a risk of death due to infection resulting from a contaminated hematopoietic stem/progenitor cell transplant of approximately 0.14 percent (26 deaths / 18,123 hematopoietic stem/progenitor cell transplants). FDA currently has no basis for predicting how many of these deaths might be avoided through implementation of the CGTP final rule.

As bacterial contamination has also been documented in studies of cord blood processing, the CGTP requirements for staff training and process validation will likely support risk and cost reduction efforts across the 25 CBSC establishments. For example, a study by Kogler et al. (Ref. 18) found that, during the initial 6 months of a CB collection program, the median bacterial contamination rate was 18 percent. After extensive training in sterile procedures for the staff who collect cord blood, the contamination rate was reduced to 1 percent. Due to a lack of data regarding the incidence and risks associated with CBSC procedures, FDA currently has no basis for predicting the magnitude of benefits that might be realized from implementation of the CGTP final rule in this HCT/P industry sector.

D. Summary of cGTP Benefits

This analysis of the potential benefits of the CGTP final rule has considered its impact on major sectors of the HCT/P industry by focusing on problems associated with HCT/Ps cited in the literature, and the costs of correcting those problems. This review suggests that current industry voluntary standards are not followed uniformly, and that implementation of the CGTP final rule has the potential to generate economic benefits by reducing communicable disease transmission risks, improving product safety, and by reducing the costs associated with correcting HCT/P related problems.

Table 13 of this document provides a summary of the particular products, problems identified and their associated costs based on the agency's survey of the literature. FDA estimated the associated health care costs based on reported risks, national level database estimates of the numbers of patients undergoing related procedures, and estimates of the direct medical costs associated with those procedures. These estimates also reflect the cost of work loss experienced by patients undergoing treatment to correct HCT/P related problems.

Rather than attempting to generate point estimates of the benefits of the CGTP rule, the agency has chosen to present the results of this analysis of potential benefits in cost-effectiveness or break-even terms. There are several reasons for this. First, the current or baseline risks associated with the various types of HCT/Ps are unknown because the data required to establish these risks is either not readily available or is not currently collected by any entity. The lack of comprehensive risk data for the HCT/P industry is due primarily to a lack of mandatory reporting requirements for adverse health events associated with human tissues, a situation that is addressed by the reporting requirements of the CGTP final rule. Second, given that the current baseline risks associated with various types of HCT/Ps are uncertain, FDA has no basis for determining defensible estimates of the degree to which implementation of the CGTP final rule might be expected to reduce these already uncertain risks. Finally, while limited data with which to characterize a few of the risks associated with a select few of the many and diverse HCT/Ps, it is not possible to fully characterize all of the potential problems associated with all of the HCT/Ps that would be affected by this rule. Thus, it is not possible to develop comprehensive estimates of the aggregate benefits of the CGTP final rule.

TABLE 13.—SUMMARY OF CGTP BENEFITS

HCT/P Industry Sector	HCT/P-Related Problem	Avoided Treatment Outcome	Estimated Cost of Treatment	Cost-Effective Percent Reduction in Cost/Risk
Eye Tissue	Primary Corneal Graft Failure	Repeat Surgery	$.729 to $6.5 million $15,844 per case	25%
Conventional Tissue	Bone Allograft Infection/Graft Failure	Repeat Surgery/Amputation	$62 million $24,587 per case	3.2%

TABLE 13.—SUMMARY OF CGTP BENEFITS—Continued

HCT/P Industry Sector	HCT/P-Related Problem	Avoided Treatment Outcome	Estimated Cost of Treatment	Cost-Effective Percent Reduction in Cost/Risk
Conventional Tissue	Heart Valve Fungal Endocarditis	Repeat Surgery (Death)	$1.2 to $1.5 million $87,204 per case	3.3%
Hematopoietic Stem/Progenitor Cells	PBSC Transplant Infection	Hospitalization (Death)	$1.4 million $24,053 per case 26 deaths	Unable to Determine

Additional uncertainties associated with estimating the benefits of the CGTP final rule include: The actual extent of current compliance in each of the affected industry sectors, the direct impact of HCT/P related problems on patient outcomes, and the precise size of the affected patient populations. Because of the limits of available data, the forgoing analysis has focused on a limited set of HCT/Ps. It is not certain how well these data represent the most critical areas, or actual levels of risk, associated with the many and varied products produced by the HCT/P industry. For some products, such as demineralized bone, the industry has achieved important advances in processing that have improved the safety and effectiveness of products. Thus, the analysis of benefits based on problem reports from several years ago, may overstate the potential for improvements in the current industry practice. In other cases, the publication of the recent reports suggests that deficiencies still exist within current practices. These areas present important opportunities to avoid product failures due to HCT/P-related problems, which lead to unnecessary communicable disease transmission risks and greater health care costs.

E. Small Entity Impacts

The Regulatory Flexibility Act requires agencies to assess whether a rule may have a significant economic impact on a substantial number of small entities. Based on size standards established by the SBA, a small establishment in this industry sector (NAICS code 621991, Blood and Organ Banks) has annual receipts of less than $8.5 million (Refs. 21 and 22). In every sector of the HCT/P industry, the majority of establishments are estimated to be classified as small entities. However, because of the large number of entities currently following industry voluntary standards, the increase in costs is expected to be limited primarily to establishments that do not follow those existing standards. To assess the impact of the CGTP rule on small businesses, FDA first calculated the ratio of average compliance costs to average annual revenues, assuming that all establishments will incur similar costs. The small entity impacts estimated below also focus on establishments that will be newly compliant under the CGTP final rule, and thus will experience the greatest potential new cost burden. Although current quality management practices at nonaccredited establishments may vary, and not every facility will incur every new cost estimated in table 4 of this document, the analysis that follows also considers a worst-case scenario in which every estimated cost is incurred by an establishment, to provide additional insight as to the maximum potential impact on small entities. While some firms may have lower than estimated average revenues, making them potentially more sensitive to cost increases, FDA does not know the distribution of firms by revenues because this information is not readily available. Therefore, the agency requested detailed industry comment regarding our average annual revenue assumptions in the CGTP proposed rule. To the extent possible, information obtained during the comment period has been incorporated into this analysis of the small entity impacts of the CGTP final rule. The results of this analysis are summarized in table 14 of this document.

A 1995 study of conventional tissue banks (Ref. 19) reports average annual revenues of $1.23 million per establishment, which translates into $1.45 million per establishment (in the year 2002 dollars) based on inflation data reported by the Bureau of Labor Statistics (Ref. 27). Most eye banks, conventional tissue banks and hematopoietic stem/progenitor cell establishments were assumed to have a comparable level of average revenues in the proposed rule, and that assumption is retained here.

Within the eye banking industry, experts estimate that virtually all of the 134 establishments would be classified as small, and all are believed to follow the current industry (EBAA) standards. The average annual revenue per eye bank is estimated at $1.45 million. If an eye bank were to incur every new cost estimated for establishments in that industry sector, the total cost impact, including total one-time and annual costs, would be $39,750, which represents 2.7 percent ($39,750 / $1.45 million) of estimated annual revenues. Average annualized compliance costs are estimated to be $12,087 ($1,619,659 total annualized costs / 134 small eye banks), and represents 0.83 percent ($12,087 / $1.45 million) of average annual revenues per firm.

In the conventional tissue banking industry, an estimated 75 to 80 percent of the total of 166 establishments may be classified as small entities. Industry experts also estimate that 75 to 80 percent of those establishments currently follow AATB standards, which generally meet or exceed the requirements of the CGTP final rule. Based on the assumed levels of increased effort and costs shown in table 4 of this document, the remaining 20 to 25 percent of small establishments that do not follow current AATB standards could incur up to $66,621 in total incremental costs, including both one-time and annual costs, assuming that every potential area of new quality management effort will be needed under the worst-case scenario. The average annual revenue per small conventional tissue bank is estimated at $1.45 million. Thus, the estimated maximum potential new costs would represent approximately 4.6 percent ($66,621 / $1.45 million) of this average annual revenue figure. The average total annualized cost for a small conventional tissue bank is estimated to be $11,678 ($1,506,433 total annualized costs / 129 small conventional tissue banks), and represents 0.8 percent ($11,678 / $1.45 million) of average annual revenues.

The agency estimates that approximately 250 hematopoietic stem/progenitor cell establishments may be classified as small entities, and that these establishments have average annual revenues of $1.45 million. An

estimated 200 (or 80 percent) of these small establishments follow the current FACT or AABB standards but will incur some additional costs. If one of these establishments were to incur new costs for each of the relevant provisions identified in table 4 of this document, the total incremental cost per establishment, including total one-time and annual costs, would be approximately $21,602. This figure represents approximately 1.5 percent ($21,602 / $1.45 million) of estimated annual revenues. The estimated 50 (or 20 percent of) small hematopoietic stem/progenitor cell establishments that do not currently comply with AABB or FACT standards will incur greater costs, as shown in table 4 of this document. If one of these establishments were assumed to incur every new cost identified in the cost analysis, the total one-time and annual costs would be approximately $83,483. This represents approximately 5.8 percent ($83,483 / $1.45 million) of average annual revenues.

The average annualized costs incurred by small hematopoietic stem/progenitor cell establishments would also vary depending on current practices and the degree to which establishments follow AABB or FACT standards. If a small hematopoietic stem/progenitor cell establishment is currently following industry standards, the average annualized cost associated with the CGTP final rule is estimated to be $8,367 ($1,673,301 total annualized costs / 200 small hematopoietic stem/progenitor cell establishments), and represents approximately 0.58 percent ($8,367 / $1.45 million) of the average annual revenue of these firms. However, if a small establishment is not following the current industry standards, a greater level of new effort will be required for quality assurance and quality management. The average annualized cost per small establishment not following current industry standards is estimated to be $43,207 ($2,160,341 total annualized costs / 50 small hematopoietic stem/progenitor cell establishments), and represents about 3 percent ($43,207 / $1.45 million) of average annual revenue.

Consultants estimate that two-thirds of all ART establishments could be classified as small entities, and have average annual revenues of approximately $2.1 million. A typical ART establishment is expected to incur average annual and annualized costs of $768. This figure represents approximately 0.04 percent ($768 / $2.1 million) of average annual revenues.

According to estimates by a semen banking industry expert, approximately 100,000 total daily intake (TDI) units are produced each year from collected and processed semen donations. An estimated 95 percent of that total production is handled by the largest 20 commercial establishments. Nineteen of these largest 20 establishments are estimated to have average annual revenues of approximately $2.4 million, and only 1 establishment is estimated to have revenues greater than $8.5 million per year. The remaining 5 percent of industry production, or 5,000 TDI units, are processed by very small semen banks that typically function within a physician office practice (e.g., that of an obstetrician/gynecologist (Ob/Gyn)). Semen banking in these establishments is generally offered as an additional service to patients receiving fertility treatment, and is not a primary line of business.

The annual revenue for these individual physician practices is estimated to be $692,000 per year, based on the average annual practice revenue per self-employed physician in the Ob/Gyn specialty category reported as $627,000 in 1998 (Ref. 20), adjusted to year 2002 dollars based on inflation data reported by the Bureau of Labor Statistics (Ref. 27). Thus the majority of semen banks would be considered small entities.

The average annual and annualized costs associated with the inspection and enforcement provisions are estimated to be $768 per affected ART establishment and semen bank. This figure represents approximately 0.03 percent ($768 / $2.4 million) of average annual revenues for the 19 small commercial semen banks, and about 0.11 percent ($768 / $692,000) for individual Ob/Gyn ART establishments and small physician practice-based semen banks.

Although these cost figures account for a much larger percentage of individual physician practice income, the semen banking provided by these establishments is considered to represent a small part of their overall business. For the smallest banks, the estimated 5,000 TDI units supplied by the estimated 90 establishments in this category translate to an average volume of 55 units per establishment per year. With an estimated price of $95 to $145 per TDI unit (Ref. 30) and an estimated profit of 15 percent, these banks would realize, on average, a net income of $12.40 to $19.00 per unit, or a total net income of $682 to $1,045 for 55 units. This income would represent only 0.1 percent ($682 / $692,000) to 0.15 percent ($1,045 / $692,000) of the estimated annual practice revenue per self-employed physician in the Ob/Gyn specialty category.

In summary, the majority of establishments within each sector of the HCT/P industry are expected to qualify as small business entities. The actual cost impact on these entities is uncertain, because of the limited information available with which to describe current practices and the degree to which individual establishments follow voluntary industry standards within each HCT/P industry sector. Based on the limited available data and industry expert opinions, the agency estimates impacts that would result in an average annualized cost per small establishment subject to CGTPs in their entirety ranging from $8,367 to $12,087 for establishments that currently follow industry standards, and $43,207 for establishments that do not currently follow industry quality standards. These annualized costs represent 0.6 percent to 0.83 percent of estimated average annual revenues for firms currently following industry standards, and 3 percent of average annual revenues for firms not following industry standards.

The worst-case analysis assumes that an affected small entity will incur new costs for every provision of the CGTP final rule. While this represents a highly unlikely scenario for nearly all firms in the HCT/P industry sectors subject to CGTPs in their entirety, this analysis does provide a useful illustration of the maximum potential burden of the CGTP final rule. The agency estimates worst-case average annualized costs per small establishment ranging from $21,602 to $66,621 for establishments that currently follow industry standards, and $83,483 for establishments that do not currently follow industry quality standards. These worst-case annualized costs for small entities, expressed as a percentage of estimated average annual revenue, range from 1.5 percent to 4.6 percent for firms currently following industry standards, and represent 5.8 percent of estimated average annual revenues for firms not following industry standards.

Establishments handling reproductive tissue are subject only to the inspection and enforcement provisions of the CGTP final rule as they apply to donor eligibility requirements under subpart C of part 1271. Small ART establishments and semen banks are expected to incur average annualized costs of $768, which represent between 0.03 and 0.11 percent of average annual revenues. The results of FDA's analysis of small entity impacts are summarized in table 14 of this document.

TABLE 14.—SUMMARY OF SMALL BUSINESS IMPACTS

No. of Small Establishments by Industry Sector	Average Annual Revenue per Small Establishment (in millions)	Average Annualized Cost per Small Establishment	Average Annualized Cost as a Percentage of Average Revenue	Worst-Case Costs for an affected Small Establishment	Worst-Case Costs as a Percentage of Average Revenue
Eye Banks (134 Establishments)	$1.45	$12,087	0.83%	$39,750	2.7%
Conventional Tissue (129 Establishments)	$1.45	$11,678	0.8%	$66,621	4.6%
Stem/Progenitor Cell Establishments Following Industry Standards (200 Establishments)	$1.45	$8,367	0.6%	$21,602	1.5%
Stem/Progenitor Cell Establishments Not Following Industry Standards (50 Establishments)	$1.45	$43,207	3%	$83,483	5.8%
ART Establishments (260 Establishments)	$2.1	$768	0.04%	$768	0.04%
Ob/Gyn and small physician based practices	$0.692	$768	0.11	$768	0.11
Semen Banks (19 Establishments)	$2.4	$768	0.03%	$768	0.03%

The agency is uncertain about the accuracy of these estimates, however, because of the lack of revenue data for individual establishments. Because of the importance of this information in accurately assessing the impact on small entities, the agency requested detailed industry comment on individual firm revenues, the percentage of establishments that qualify as small entities, the percentage of those establishments that comply with current industry quality standards and the extent of their compliance, and the specific areas where industry anticipates substantial differences between current manufacturing practices and the quality assurance elements specified under the CGTP final rule. For those areas of identified difference, the agency further requested estimates of the resources and costs required for establishment compliance. This analysis has incorporated information received during the comment period to the extent possible. Please see our responses to comments 172 through 197 at section III.F. of this document for details.

Although the CGTP final rule will impose some costs on small entities involved in the manufacture of HCT/Ps, the agency believes that this approach represents an effective means of protecting patient safety and public health. The less burdensome alternatives to the CGTP final rule involve fewer requirements for small entities (the vast majority of entities in this industry), but fail to provide fundamental assurances of product quality and safety. Reliance on industry professional organization voluntary standards or published FDA guidance for good tissue practice, rather that establishing a regulatory requirement, would not ensure uniform or consistent compliance and would preclude the agency's ability to effectively monitor HCT/Ps to ensure public health and safety. Given that each trade organization varies in their standards or guidelines, regulatory requirements for good tissue practice would help to ensure consistency among manufacturers and across the various sectors of the HCT/P industry. Further, the adverse reaction reporting requirements of the CGTP final rule will provide valuable information that will allow the agency to identify and respond to emerging public health and safety risks associated with HCT/Ps. FDA finds that the CGTP final rule will enhance both public health and public confidence in the safety and quality of the nation's supply of HCT/Ps, while imposing only a minimum burden on the affected entities.

Another alternative would involve waiving some of the requirements for small establishments. However, as noted previously, nearly all establishments in this industry are small. Moreover, this alternative would increase HCT/P safety risks if small establishments that currently follow voluntary industry standards for good tissue practice choose to discontinue this practice due to an FDA-granted waiver. Furthermore, documentation and record retention provisions ensure that HCT/Ps can be tracked to their source in the event of infection or other adverse reactions that result from donor tissue characteristics.

In summary, the agency believes that abridged requirements for CGTP, based on voluntary standards or facility size criteria, would provide inadequate protection against the risk of communicable disease transmission. Most notably, the current absence of regulation allows some establishments handling human tissues to ignore the standards established by industry professional associations and followed by a majority of entities in all sectors of the HCT/P industry.

FDA has made a number of revisions to this final rule, many in response to public comments on the proposed CGTP rule, that are expected to reduce the overall compliance burden on affected entities.

Provisions under § 1271.160(c) have been revised to require audits periodically rather than annually as stipulated under the CGTP proposed rule. However, the cost estimates presented in this analysis of economic impacts retain the assumption that audits will impose an annual burden so as to generate conservative estimates of overall compliance costs. The provisions proposed under § 1271.160(f), requiring complete validation of custom computer software used for making HCT/P-related decisions or determinations, have been changed to a requirement for validation or verification as appropriate.

Verification is a less burdensome alternative that would apply to software not relied upon for making donor eligibility or HCT/P suitability decisions or determinations (e.g., inventory).

The proposed requirement under § 1271.180 for an annual review of all procedures has been removed, as has the requirement for prior authorization of any deviation from an established procedure. Provisions proposed under § 1271.220(b) (process controls) requiring procedures for the use and removal of processing material have been deleted in response to comments. Proposed provisions under § 1271.230(e) requiring validation of all process changes and process deviations now require validation only of process changes. Requirements proposed under § 1271.265(e) for HCT/P packaging validation now allow for packaging validation or verification (a less burdensome alternative) as appropriate.

Provisions proposed under § 1271.290(d) and (e) requiring establishments to ensure each HCT/P is tracked from donor to recipient and from recipient to donor, now only require that establishments have a method of tracking in place. This will reduce the burden on affected entities because they no longer bear the responsibility of ensuring tracking with respect to their consignees. The proposed requirement for the reporting of all HCT/P deviations under § 1271.350(b) now only applies to distributed HCT/Ps and not to those still in inventory. Finally, language has been added to § 1271.420(b) to allow transportation to the consignee under quarantine of HCT/Ps offered for import to facilitate more rapid release of imported tissue products.

As part of the development process for this final rule, FDA conducted an extensive outreach program in an effort to inform affected small entities and to request input regarding the potential economic impact. Representatives from CBER have given presentations on good tissue practice related issues at the annual conferences of many of the professional associations representing affected entities including ASRM, AATB, EBAA, and others. The agency has also engaged in outreach activities directed toward interested consumer groups such as RESOLVE and the American Infertility Association. At their request, FDA also held individual meetings with ASRM, EBAA, and AATB to discuss specific concerns regarding the impact of the CGTP rule. Some of these presentation materials and meeting minutes are available on the CBER Web page at *http://www.fda.gov/cber/tissue/min.htm*. Additional materials associated with the CGTP rule are available online at *http://www.fda.gov/cber/tissue/docs.htm*. Finally, in the proposed rule, FDA requested industry comment regarding the many assumptions upon which this analysis of economic impacts was based. In particular, we requested detailed industry comment regarding our estimates of: The number and type of entities affected, the extent of CGTP, compliance rates for firms in various sectors of the HCT/P industry, and the level of compliance costs. To the extent possible, we have incorporated these comments and our responses into the preamble and analysis of economic impacts of this final rule.

The specific requirements for good tissue practice, the required recordkeeping, and the required types of professional skills are described in the economic analysis provided previously. This analysis includes an accounting of all major cost factors, with the exception of the reduced potential liability currently encountered by those marginal tissue establishments that fail to provide the level of protection from infectious disease that is considered a standard of good practice in other sectors of the tissue-based product industry. The relevant Federal rules that are related to this final rule are discussed in section II of this document. This economic analysis provides a summary of the private industry standards that overlap this final Federal standard, but as discussed, there is no current regulation of tissue that will duplicate this final rule. Consequently, FDA finds that this final rule will enhance both public health and public confidence in the safety and utility of HCT/Ps, while imposing only a minimum burden on the affected industry sectors.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (j) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

VII. Federalism Assessment

Executive Order 13132, dated August 4, 1999, establishes the procedure that Federal agencies must follow when formulating and implementing policies that have federalism implications. The Executive order described nine fundamental federalism principles, stressing the importance and sovereignty of State and local governments, and the contributions of individual states and communities to the development of enlightened public policy. Principles of federalism are inherent in the very structure of the Constitution and formalized in and protected by the tenth amendment. Regulations have federalism implications whenever they have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Whenever a regulation has this result, the agency must prepare a federalism assessment.

The Executive order directs Federal agencies to:

- Encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States;
- Where possible, defer to the States to establish standards;
- In determining whether to establish uniform national standards, consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority; and
- Where national standards are required by Federal statutes, consult with appropriate State and local officials in developing those standards.

In the proposed rule (66 FR 1508 at 1551), we made the statement that we had analyzed the proposed rule in accordance with the principles set forth in Executive Order 13132, and that the proposed rule may raise federalism implications because it could preempt States' laws regarding donated human cells and tissues. We then invited comments from elected State and local government officials on:

- The need for the proposed CGTP to prevent communicable disease transmission through HCT/Ps;
- Alternatives that would limit the scope of such national requirements or otherwise preserve State prerogatives and authority;
- The proposed CGTP provisions; and
- Any other issues raised by the proposed rule that could affect State laws and authorities.

We received no comments from State officials on federalism issues.

This final rule represents the exercise of a core Federal function: ''prevent[ing] the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession'' (section 361(a) of the PHS

Act; 42 U.S.C. 264). To prevent the transmission of communicable disease in the United States, including the interstate transmission of disease, uniform national standards for HCT/Ps are necessary. No State official commented otherwise. For these reasons, this rule is consistent with the federalism principles expressed in Executive Order 13132.

However, we received two comments requesting that we clearly state that this rulemaking's provisions preempt state tissue regulations.

We decline to make this statement. Section 361 was recently amended to provide,

> Nothing in this section or section 363 [42 U.S.C. 266], or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 363.

(section 361(e); 42 U.S.C. 264(e)).

Accordingly, consistent with this provision, establishments must comply with applicable State law and regulations, unless the State provisions conflict with this exercise of Federal authority under section 361. In the event of such a conflict, these regulations would preempt the State provisions under ordinary principles of preemption. (*Geier* v. *Honda*, 529 U.S. 861 (2000).)

VIII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is shown as follows with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement.

Description: Under the authority of section 361 of the PHS Act, FDA is requiring certain HCT/P establishments to follow CGTP, which includes information collection provisions such as the establishment and maintenance of SOPs, recordkeeping, reporting, and labeling of the HCT/Ps. The CGTP information collection provisions in this rulemaking provide: (1) Additional measures for preventing the introduction, transmission, or spread of communicable diseases; (2) step-by-step consistency in the manufacturing of the HCT/P; (3) necessary information to FDA for the purpose of protecting public health and safety; (4) accountability in the manufacturing of HCT/Ps; and (5) information facilitating the tracking of an HCT/P back to its original source or to a consignee.

Table 15 lists provisions that require reporting or disclosure of information to third parties, the Federal Government, or the public. Section 1271.155(a) permits the submission of a request for FDA approval of an exemption or an alternative from any requirement in subpart C or D of part 1271. Section 1271.290(c) requires the establishment to affix a distinct identification code to each HCT/P relating the HCT/P to the donor and all records pertaining to the HCT/P. Whenever an establishment initially distributes an HCT/P to a consignee, § 1271.290(f) requires the establishment to inform the consignee, in writing, of the product tracking requirements and the methods the establishment uses to fulfill the requirements. Non-reproductive HCT/P establishments described in § 1271.10 are required under § 1271.350(a)(1) and (b)(1) to report to FDA adverse reactions (defined in § 1271.3(y)) and HCT/P deviations (defined in § 1271.3(dd)). Section 1271.370(b) and (c) requires establishments to include specific information either on the HCT/P label or in the package insert.

Table 16 lists recordkeeping provisions under this final rule. Nonreproductive HCT/P establishments are required to prepare and maintain written SOPs to meet the core CGTP requirements for all steps performed in the manufacturing of HCT/Ps. As calculated in table 16 of this document, the preparation of the SOPs would result in a one-time impact on establishments and, once composed and/or reviewed for compliance, SOPs would only be updated as necessary.

The requirement for reporting, SOPs, and recordkeeping in proposed §§ 1271.160(d)(3), 1271.160(f), 1271.170(d), 1271.195(a), 1271.210(a) and (b), 1271.220(b), 1271.225(b), 1271.230(b) and (d), 1271.270(c), 1271.290(f), and 1271.350(c) are not included in the final rule.

The SOP provisions under part 1271 include: (1) § 1271.160(b)(2) (receiving, investigation, evaluating, and documenting information relating to core CGTP requirements received from other sources and for sharing information with consignees and other establishments); (2) § 1271.180(a) (to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps); (3) § 1271.190(d)(1) (facility cleaning and sanitization); (4) § 1271.200(b) (cleaning, sanitizing, and maintenance of equipment); (5) § 1271.200(c) (calibration of equipment); (6) § 1271.230(a) (verification or validation of changes to a process); (7) § 1271.250(a) (controls for labeling HCT/Ps); (8) § 1271.265(e) (receipt, pre-distribution shipment, availability for distribution, and packaging and shipping of HCT/Ps); (9) § 1271.265(f) (suitable for return to inventory); (10) § 1271.270(b) (records management system); (11) § 1271.290(b)(1) (system of HCT/P tracking); and, (12) § 1271.320(a) (review, evaluation, and documentation of all complaints).

Part 1271 requires the following additional recordkeeping provisions listed under Table 16. Section 1271.155(f) requires an establishment operating under the terms of an exemption or alternative to maintain documentation of the terms and date of FDA approval. Section 1271.160(b)(3) requires documentation of corrective actions taken as a result of an audit of the quality program. Section 1271.160(b)(6) requires documentation of HCT/P deviations. Section 1271.160(d) requires documentation of computer validation or verification activities and results when computers are used to comply with the core CGTP requirements for its intended use. Section 1271.190(d)(2) requires documentation of all significant facility cleaning and sanitation. Section 1271.195(d) requires documentation of environmental control and monitoring activities. Section 1271.200(e) requires documentation of all equipment maintenance, cleaning, sanitizing, calibration, and other activities. Section 1271.210(d) requires documentation of the receipt, verification, and use of each supply or reagent. Section 1271.230(a) requires documentation of validation activities when the results of a process cannot be fully verified by subsequent inspection and tests. Section 1271.230(c) requires documentation of the review and evaluation of a process and revalidation of the process, if necessary, when any changes to a validated process occur. Sections 1271.260(d) and (e) require documentation of the storage temperature of HCT/Ps and any corrective action taken when acceptable storage conditions are not met. Section 1271.265(c)(1) requires documentation that all release criteria are met before distribution of an HCT/P. Section

1271.265(c)(3) requires documentation of any departure from a procedure at the time of occurrence. Section 1271.265(e) requires documentation of the receipt, pre-distribution shipment, distribution, and packaging and shipping of HCT/Ps. Section 1271.270(a) requires documentation of each step in manufacturing required in subparts C and D.

Section 1271.270(e) requires documentation of the name and address, and a list of responsibilities of any establishment that performs a manufacturing step for you. Sections 1271.290(d) and (e) require documentation of the disposition of each non-reproductive HCT/P as part of its tracking method. Section 1271.320(b) requires an establishment to maintain a record of each complaint that it receives, including a review and evaluation.

Section 1271.270(d) requires the retention of all records for a period of 10 years after their creation. Records pertaining to a particular nonreproductive HCT/P are required to be retained at least 10 years after the date of administration. If the date of administration is not known, then records are required to be retained at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest. This retention time is necessary because certain nonreproductive HCT/Ps have long storage periods. In addition, advances in medical technology have created opportunities for diagnosis and therapy for up to 10 years after recipient exposure to an HCT/P from a donor later determined to be at risk for communicable disease agents or diseases.

Description of Respondents: For-profit and not-for-profit institutions.

As required by section 3506(c)(2)(B) of the PRA, we provided an opportunity for public comment on the information collection requirements of the proposed rule (66 FR 1508 at 1548). No comments on the information collection burden estimate were submitted to the docket. However, we respond to comments on the utility of the information collection in section III of this document, e.g., response to comment 68 addresses the utility and burden of retaining facility cleaning and sanitation records for 10 years.

FDA estimates the burden of this collection of information as follows:

TABLE 15.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1271.155(a)	1,302	1	1,302	3	3,906
1271.290(c)	93	52.2	4,855	0.08	388
1271.290(f)	227	1	227	1	227
1271.350(a)(1)	792	6	4,752	1	4,752
1271.350(b)(1)	792	2	1,584	1	1,584
1271.370(b) and (c)	93	52.2	4,855	0.25	1,214
Total					12,071

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 16.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
One-time Burden (Creation of SOPs)	93	12	1,116	16	17,856
	134	3	402	16	6,432
One-time Burden (Review of existing SOPs for compliance)	699	12	8,388	8	67,104
	134	9	1,206	8	9,648
SOP Maintenance (See previous list of 12 SOPs)	792	12	9,504	2	19,008
1271.155(f)	792	1	792	0.25	198
1271.160(b)(3)	93	12	1,116	1	1,116
1271.160(b)(6)	227	12	2,724	1	2,724
1271.160(d)	227	12	2,724	1	2,724
1271.190(d)(2)	93	12	1,116	1	1,116
1271.195(d)	227	12	2,724	1	2,724
1271.200(e)	93	12	1,116	1	1,116

TABLE 16.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1271.210(d)	93	12	1,116	1	1,116
1271.230(a)	227	12	2,724	1	2,724
1271.230(c)	360	1	360	1	360
1271.260(d)	227	12	2,724	0.25	681
1271.260(e)	93	365	33,945	0.08	2,716
1271.265(c)(1)	227	1,079.8	245,105	0.08	19,608
1271.265(c)(3)	592	1	592	1	592
1271.265(e)	93	1,622.6	150,905	0.08	12,072
1271.270(a)	227	1,079.8	245,105	0.25	61,276
1271.270(e)	227	2	454	0.5	227
1271.290(d) and (e)	93	1,622.6	150,905	0.25	37,726
1271.320(b)	93	5	465	1	465
Total					271,329

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Under this final rule, 12 SOPs are required as previously described. FDA is assuming that approximately 93 nonreproductive HCT/P establishments would create all 12 SOPs, and 134 nonreproductive HCT/P establishments would create 3 SOPs, for a total of 1,518 records; and we estimate that it would take 16 hours per new SOP for a total of 24,288 hours as a one-time burden. We estimate that up to 12 SOPs would already exist for each nonreproductive HCT/P establishment as a result of complying with current applicable regulations or following industry organizational standards. We estimate that approximately 699 nonreproductive HCT/P establishments would review all 12 SOPs, and 134 nonreproductive HCT/P establishments would revise 9 SOPs. Each review would take approximately 8 hours per SOP for a total one-time burden of 76,752 hours.

Once the SOPs are created, annual SOP maintenance of existing SOPs is estimated to involve 2 hours annually per SOP. An additional hour for clerical time is added to the 1 hour per SOP stated in the proposed rule. Annual total hours for maintaining the SOPs is estimated at 19,008 hours.

In some cases, the estimated burden may appear to be lower or higher than the burden experienced by individual establishments. The estimated burden in these charts is an estimated average burden, taking into account the range of impact each regulation may have. In estimating the burden, FDA compared the regulations with the current voluntary standards of a number of industry organizations, such as, AATB, EBAA, AABB, FACT, NMDP, and CAP. In those cases where a voluntary industry standard appears to be equivalent to a regulation, FDA has assumed that any reporting or recordkeeping burden is a customary and usual business practice of establishments who are members of those organizations and no additional burden is calculated here. In some cases establishments affected by this rule may already be required to comply with regulations for manufacturers of human drugs or biological products, e.g., 21 CFR parts 210, 211, 312, 314, 600, and 606. FDA attributes the decrease in total burden hours in the final rule (283,400 hours) from the total burden hours in the proposed rule (621,573 hours) to:

- Not including certain proposed information collection burden in the final rule;
- Not applying the information collection burden to reproductive HCT/P establishments; and
- Industry strengthening their current standards.

FDA has estimated the reporting (table 15 of this document) and recordkeeping (table 16 of this document) burdens based upon our institutional experience with comparable recordkeeping and reporting provisions applicable to the human drug and biological product industries, recent information from trade organizations related to the manufacturing of non-reproductive HCT/Ps utilizing cells and tissues, and data provided by the Eastern Research Group (ERG), a consulting firm hired by FDA to prepare an economic analysis of the potential economic impact on semen banks and ART facilities.

We have estimated that there are approximately 792 nonreproductive HCT/P manufacturers (approximately 166 conventional tissue establishments, 134 eye tissue establishments, 425 peripheral and cord blood stem/progenitor cells, and 67 manufacturers of licensed biological products or devices). For the number of respondents for requesting a variance under § 1271.155(a) in table 15 of this document, we added 510 reproductive HCT/P establishments. FDA obtained these estimates of manufacturers (including percentage of members and nonmembers) from the various trade organizations and our registration systems for HCT/P, biological product, and device manufacturers. The total number of respondents and recordkeepers, 1,302, in the tables is decreased for each provision by the estimated number of establishments that follow, as usual and customary practice, the applicable established trade

organizational standards comparable to the GTP requirements, i.e., AATB, EBAA, FACT, AABB, NMDP, or CAP. FDA based the estimated numbers for ''Number of Respondents'' and ''Number of Recordkeepers'' on information provided by the trade organizations and FDA registration databases.

FDA based the estimated numbers for ''Annual Frequency per Response,'' ''Total Annual Responses,'' ''Annual Frequency per Recordkeeping,'' and ''Total Annual Records'' on information received from the trade organizations, institutional experience with similar requirements (Good Manufacturing Practice), general information provided to FDA during inspections of manufacturers of human tissue intended for transplantation, and information gathered by ERG.

The estimates for ''Hours per Response'' or ''Hours per Record'' were calculated using comparable burdens under drug GMP regulations (21 CFR part 211) and GMP for blood and blood components (21 Part 606) or by using the information provided by ERG, e.g., time spent on §§ 1271.190(c)(4) (documentation of cleaning and sanitation) and 1271.195(c) (documentation of environmental control and monitoring activities) was an estimate provided by ERG.

The information collection requirements of this final rule have been approved by OMB. The OMB control number is 0910–0559; it expires 11/30/07. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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List of Subjects

21 CFR part 16

Administrative practice and procedure.

21 CFR part 1270

Communicable diseases, HIV/AIDS, Reporting and recordkeeping requirements.

21 CFR part 1271

Communicable diseases, HIV/AIDS, Human cells, tissues, and cellular and tissue-based products, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, Chapter I of title 21 of the Code of Federal Regulations is amended as follows:

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 1271.440(e) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1271.440(e) relating to the retention, recall, and destruction of human cells, tissues, and cellular and tissue-based products (HCT/Ps), and/or the cessation of manufacturing HCT/Ps.

PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

■ 3. The authority citation for 21 CFR part 1270 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

■ 4. Section 1270.3 is amended by revising paragraph (j) introductory text to read as follows:

§ 1270.3 Definitions

* * * * *

(j) *Human tissue, for the purpose of this part* means any tissue derived from a human body and recovered before May 25, 2005, which:

* * * * *

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 5. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

■ 6. Section 1271.3 is amended by revising paragraphs (c) and (d) and by adding paragraphs (y) through (ll) to read as follows:

§ 1271.3 How does FDA define important terms in this part?

* * * * *

(c) *Homologous use* means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

(d) Human cells, tissues, or cellular or tissue-based products (HCT/Ps) means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The following articles are not considered HCT/Ps:

(1) Vascularized human organs for transplantation;

(2) Whole blood or blood components or blood derivative products subject to listing under parts 607 and 207 of this chapter, respectively;

(3) Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered an HCT/P;

(4) Minimally manipulated bone marrow for homologous use and not combined with another article (except for water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow);

(5) Ancillary products used in the manufacture of HCT/P;

(6) Cells, tissues, and organs derived from animals other than humans; and

(7) In vitro diagnostic products as defined in § 809.3(a) of this chapter.

* * * * *

(y) *Adverse reaction* means a noxious and unintended response to any HCT/P for which there is a reasonable possibility that the HCT/P caused the response.

(z) *Available for distribution* means that the HCT/P has been determined to meet all release criteria.

(aa) *Complaint* means any written, oral, or electronic communication about a distributed HCT/P that alleges:

(1) That an HCT/P has transmitted or may have transmitted a communicable disease to the recipient of the HCT/P; or

(2) Any other problem with an HCT/P relating to the potential for transmission of communicable disease, such as the failure to comply with current good tissue practice.

(bb) *Distribution* means any conveyance or shipment (including importation and exportation) of an HCT/P that has been determined to meet all release criteria, whether or not such conveyance or shipment is entirely intrastate. If an entity does not take physical possession of an HCT/P, the entity is not considered a distributor.

(cc) *Establish and maintain* means define, document (in writing or electronically), and implement; then follow, review, and, as needed, revise on an ongoing basis.

(dd) *HCT/P deviation* means an event:

(1) That represents a deviation from applicable regulations in this part or from applicable standards or established specifications that relate to the prevention of communicable disease transmission or HCT/P contamination; or

(2) That is an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease or may lead to HCT/P contamination.

(ee) *Importer of record* means the person, establishment, or its representative responsible for making entry of imported goods in accordance with all laws affecting such importation.

(ff) *Processing* means any activity performed on an HCT/P, other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution, such as testing for microorganisms, preparation, sterilization, steps to inactivate or remove adventitious agents, preservation for storage, and removal from storage.

(gg) *Quality audit* means a documented, independent inspection and review of an establishment's activities related to core CGTP requirements. The purpose of a quality audit is to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.

(hh) *Quality program* means an organization's comprehensive system for manufacturing and tracking HCT/Ps in accordance with this part. A quality program is designed to prevent, detect, and correct deficiencies that may lead to circumstances that increase the risk of introduction, transmission, or spread of communicable diseases.

(ii) *Recovery* means obtaining from a human donor cells or tissues that are intended for use in human implantation, transplantation, infusion, or transfer.

(jj) *Storage* means holding HCT/Ps for future processing and/or distribution.

(kk) *Validation* means confirmation by examination and provision of

objective evidence that particular requirements can consistently be fulfilled. Validation of a process, or *process validation*, means establishing by objective evidence that a process consistently produces a result or HCT/P meeting its predetermined specifications.

(ll) *Verification* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

■ 7. Section 1271.10 is amended by revising paragraph (a)(3) to read as follows:

§ 1271.10 Are my HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?

(a) * * *

(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

* * * * *

■ 8. Section 1271.22 is revised to read as follows:

§ 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

(1) Establishment registration,

(2) HCT/P listings, and

(3) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(1) By writing to the Center for Biologics Evaluation and Research (HFM–775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator;

(2) By contacting any Food and Drug Administration district office;

(3) By calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800; or

(4) By connecting to *http://www.fda.gov/opacom/morechoices/fdaforms/cber.html* on the Internet.

(c)(1) You may submit Form FDA 3356 to the Center for Biologics Evaluation and Research (HFM–775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator; or

(2) You may submit Form FDA 3356 electronically through a secure web server at *http://www.fda.gov/cber/tissue/tisreg.htm*.

■ 9. Section 1271.45 is amended in paragraph (a), after the second sentence, by adding a sentence to read as follows:

§ 1271.45 What requirements does this subpart contain?

(a) * * * Other CGTP requirements are set out in subpart D of this part.

* * * * *

■ 10. Part 1271 is amended by adding subpart D, consisting of §§ 1271.145 through 1271.320, to read as follows:

Subpart D—Current Good Tissue Practice

Sec.

1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.
1271.150 Current good tissue practice requirements.
1271.155 Exemptions and alternatives.
1271.160 Establishment and maintenance of a quality program.
1271.170 Personnel.
1271.180 Procedures.
1271.190 Facilities.
1271.195 Environmental control and monitoring.
1271.200 Equipment.
1271.210 Supplies and reagents.
1271.215 Recovery.
1271.220 Processing and process controls.
1271.225 Process changes.
1271.230 Process validation.
1271.250 Labeling controls.
1271.260 Storage.
1271.265 Receipt, predistribution shipment, and distribution of an HCT/P.
1271.270 Records.
1271.290 Tracking.
1271.320 Complaint file.

Subpart D—Current Good Tissue Practice

§ 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.

You must recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in a way that prevents the introduction, transmission, or spread of communicable diseases.

§ 1271.150 Current good tissue practice requirements.

(a) *General.* This subpart D and subpart C of this part set forth current good tissue practice (CGTP) requirements. You must follow CGTP requirements to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps (e.g., by ensuring that the HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing). Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents. CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The CGTP provisions specifically governing determinations of donor eligibility, including donor screening and testing, are set out separately in subpart C of this part.

(b) *Core CGTP requirements.* The following are core CGTP requirements:

(1) Requirements relating to facilities in § 1271.190(a) and (b);

(2) Requirements relating to environmental control in § 1271.195(a);

(3) Requirements relating to equipment in § 1271.200(a);

(4) Requirements relating to supplies and reagents in § 1271.210(a) and (b);

(5) Requirements relating to recovery in § 1271.215;

(6) Requirements relating to processing and process controls in § 1271.220;

(7) Requirements relating to labeling controls in § 1271.250(a) and (b);

(8) Requirements relating to storage in § 1271.260 (a) through (d);

(9) Requirements relating to receipt, predistribution shipment, and distribution of an HCT/P in § 1271.265(a) through (d); and

(10) Requirements relating to donor eligibility determinations, donor screening, and donor testing in §§ 1271.50, 1271.75, 1271.80, and 1271.85.

(c) *Compliance with applicable requirements*—(1) *Manufacturing arrangements* (i) If you are an establishment that engages in only some operations subject to the regulations in this subpart and subpart C of this part, and not others, then you need only comply with those requirements applicable to the operations that you perform.

(ii) If you engage another establishment (e.g., a laboratory to perform communicable disease testing, or an irradiation facility to perform terminal sterilization), under a contract, agreement, or other arrangement, to perform any step in manufacture for you, that establishment is responsible for complying with requirements applicable to that manufacturing step.

(iii) Before entering into a contract, agreement, or other arrangement with another establishment to perform any step in manufacture for you, you must ensure that the establishment complies with applicable CGTP requirements. If, during the course of this contract, agreement, or other arrangement, you

become aware of information suggesting that the establishment may no longer be in compliance with such requirements, you must take reasonable steps to ensure the establishment complies with those requirements. If you determine that the establishment is not in compliance with those requirements, you must terminate your contract, agreement, or other arrangement with the establishment.

(2) If you are the establishment that determines that an HCT/P meets all release criteria and makes the HCT/P available for distribution, whether or not you are the actual distributor, you are responsible for reviewing manufacturing and tracking records to determine that the HCT/P has been manufactured and tracked in compliance with the requirements of this subpart and subpart C of this part and any other applicable requirements.

(3) With the exception of §§ 1271.150(c) and 1271.155 of this subpart, the regulations in this subpart are not being implemented for reproductive HCT/Ps described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, or for the establishments that manufacture them.

(d) *Compliance with parts 210, 211, and 820 of this chapter.* With respect to HCT/Ps that are drugs (subject to review under an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or under a biological product license application under section 351 of the Public Health Service Act) or that are devices (subject to premarket review or notification under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act), the procedures contained in this subpart and in subpart C of this part and the current good manufacturing practice regulations in parts 210 and 211 of this chapter and the quality system regulations in part 820 of this chapter supplement, and do not supersede, each other unless the regulations explicitly provide otherwise. In the event that a regulation in part 1271 of this chapter is in conflict with a requirement in parts 210, 211, or 820 of this chapter, the regulations more specifically applicable to the product in question will supersede the more general.

(e) *Where appropriate.* When a requirement is qualified by ''where appropriate,'' it is deemed to be ''appropriate'' unless you can document justification otherwise. A requirement is ''appropriate'' if nonimplementation of the requirement could reasonably be expected to result in the HCT/P not meeting its specified requirements related to prevention of introduction, transmission, or spread of communicable diseases, or in your inability to carry out any necessary corrective action.

§ 1271.155 Exemptions and alternatives.

(a) *General.* You may request an exemption from or alternative to any requirement in subpart C or D of this part.

(b) *Request for exemption or alternative.* Submit your request under this section to the Director of the appropriate Center (the Director), e.g., the Center for Biologics Evaluation and Research or the Center for Devices and Radiological Health. The request must be accompanied by supporting documentation, including all relevant valid scientific data, and must contain either:

(1) Information justifying the requested exemption from the requirement, or

(2) A description of a proposed alternative method of meeting the requirement.

(c) *Criteria for granting an exemption or alternative.* The Director may grant an exemption or alternative if he or she finds that such action is consistent with the goals of protecting the public health and/or preventing the introduction, transmission, or spread of communicable diseases and that:

(1) The information submitted justifies an exemption; or

(2) The proposed alternative satisfies the purpose of the requirement.

(d) *Form of request.* You must ordinarily make your request for an exemption or alternative in writing (hard copy or electronically). However, if circumstances make it difficult (e.g., there is inadequate time) to submit your request in writing, you may make the request orally, and the Director may orally grant an exemption or alternative. You must follow your oral request with an immediate written request, to which the Director will respond in writing.

(e) *Operation under exemption or alternative.* You must not begin operating under the terms of a requested exemption or alternative until the exemption or alternative has been granted. You may apply for an extension of an exemption or alternative beyond its expiration date, if any.

(f) *Documentation.* If you operate under the terms of an exemption or alternative, you must maintain documentation of:

(1) FDA's grant of the exemption or alternative, and

(2) The date on which you began operating under the terms of the exemption or alternative.

(g) *Issuance of an exemption or alternative by the Director.* In a public health emergency, the Director may issue an exemption from, or alternative to, any requirement in part 1271. The Director may issue an exemption or alternative under this section if the exemption or alternative is necessary to assure that certain HCT/Ps will be available in a specified location to respond to an unanticipated immediate need for those HCT/Ps.

§ 1271.160 Establishment and maintenance of a quality program.

(a) *General.* If you are an establishment that performs any step in the manufacture of HCT/Ps, you must establish and maintain a quality program intended to prevent the introduction, transmission, or spread of communicable diseases through the manufacture and use of HCT/Ps. The quality program must be appropriate for the specific HCT/Ps manufactured and the manufacturing steps performed. The quality program must address all core CGTP requirements listed in § 1271.150(b).

(b) *Functions.* Functions of the quality program must include:

(1) Establishing and maintaining appropriate procedures relating to core CGTP requirements, and ensuring compliance with the requirements of § 1271.180 with respect to such procedures, including review, approval, and revision;

(2) Ensuring that procedures exist for receiving, investigating, evaluating, and documenting information relating to core CGTP requirements, including complaints, and for sharing any information pertaining to the possible contamination of the HCT/P or the potential for transmission of a communicable disease by the HCT/P with the following:

(i) Other establishments that are known to have recovered HCT/Ps from the same donor;

(ii) Other establishments that are known to have performed manufacturing steps with respect to the same HCT/P; and

(iii) Relating to consignees, in the case of such information received after the HCT/P is made available for distribution, shipped to the consignee, or administered to the recipient, procedures must include provisions for assessing risk and appropriate followup, and evaluating the effect this information has on the HCT/P and for the notification of all entities to whom the affected HCT/P was distributed, the

quarantine and recall of the HCT/P, and/or reporting to FDA, as necessary.

(3) Ensuring that appropriate corrective actions relating to core CGTP requirements, including reaudits of deficiencies, are taken and documented, as necessary. You must verify corrective actions to ensure that such actions are effective and are in compliance with CGTP. Where appropriate, corrective actions must include both short-term action to address the immediate problem and long-term action to prevent the problem's recurrence. Documentation of corrective actions must include, where appropriate:

(i) Identification of the HCT/P affected and a description of its disposition;

(ii) The nature of the problem requiring corrective action;

(iii) A description of the corrective action taken; and

(iv) The date(s) of the corrective action.

(4) Ensuring the proper training and education of personnel involved in activities related to core CGTP requirements;

(5) Establishing and maintaining appropriate monitoring systems as necessary to comply with the requirements of this subpart (e.g., environmental monitoring);

(6) Investigating and documenting HCT/P deviations and trends of HCT/P deviations relating to core CGTP requirements and making reports if required under § 1271.350(b) or other applicable regulations. Each investigation must include a review and evaluation of the HCT/P deviation, the efforts made to determine the cause, and the implementation of corrective action(s) to address the HCT/P deviation and prevent recurrence.

(c) *Audits*. You must periodically perform for management review a quality audit, as defined in § 1271.3(gg), of activities related to core CGTP requirements.

(d) *Computers*. You must validate the performance of computer software for the intended use, and the performance of any changes to that software for the intended use, if you rely upon the software to comply with core CGTP requirements and if the software either is custom software or is commercially available software that has been customized or programmed (including software programmed to perform a user defined calculation or table) to perform a function related to core CGTP requirements. You must verify the performance of all other software for the intended use if you rely upon it to comply with core CGTP requirements. You must approve and document these activities and results before implementation.

§ 1271.170 Personnel.

(a) *General*. You must have personnel sufficient to ensure compliance with the requirements of this part.

(b) *Competent performance of functions*. You must have personnel with the necessary education, experience, and training to ensure competent performance of their assigned functions. Personnel must perform only those activities for which they are qualified and authorized.

(c) *Training*. You must train all personnel, and retrain as necessary, to perform their assigned responsibilities adequately.

§ 1271.180 Procedures.

(a) *General*. You must establish and maintain procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps. You must design these procedures to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases through the use of HCT/Ps.

(b) *Review and approval*. Before implementation, a responsible person must review and approve these procedures.

(c) *Availability*. These procedures must be readily available to the personnel in the area where the operations to which they relate are performed, or in a nearby area if such availability is impractical.

(d) *Standard procedures*. If you adopt current standard procedures from another organization, you must verify that the procedures meet the requirements of this part and are appropriate for your operations.

§ 1271.190 Facilities.

(a) *General*. Any facility used in the manufacture of HCT/Ps must be of suitable size, construction, and location to prevent contamination of HCT/Ps with communicable disease agents and to ensure orderly handling of HCT/Ps without mix-ups. You must maintain the facility in a good state of repair. You must provide lighting, ventilation, plumbing, drainage, and access to sinks and toilets that are adequate to prevent the introduction, transmission, or spread of communicable disease.

(b) *Facility cleaning and sanitation*. (1) You must maintain any facility used in the manufacture of HCT/Ps in a clean, sanitary, and orderly manner, to prevent the introduction, transmission, or spread of communicable disease.

(2) You must dispose of sewage, trash, and other refuse in a timely, safe, and sanitary manner.

(c) *Operations*. You must divide a facility used in the manufacture of HCT/Ps into separate or defined areas of adequate size for each operation that takes place in the facility, or you must establish and maintain other control systems to prevent improper labeling, mix-ups, contamination, cross-contamination, and accidental exposure of HCT/Ps to communicable disease agents.

(d) *Procedures and records*. (1) You must establish and maintain procedures for facility cleaning and sanitation for the purpose of preventing the introduction, transmission, or spread of communicable disease. These procedures must assign responsibility for sanitation and must describe in sufficient detail the cleaning methods to be used and the schedule for cleaning the facility.

(2) You must document, and maintain records of, all cleaning and sanitation activities performed to prevent contamination of HCT/Ps. You must retain such records 3 years after their creation.

§ 1271.195 Environmental control and monitoring.

(a) *Environmental control*. Where environmental conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable disease agents, you must adequately control environmental conditions and provide proper conditions for operations. Where appropriate, you must provide for the following control activities or systems:

(1) Temperature and humidity controls;

(2) Ventilation and air filtration;

(3) Cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations; and

(4) Maintenance of equipment used to control conditions necessary for aseptic processing operations.

(b) *Inspections*. You must inspect each environmental control system periodically to verify that the system, including necessary equipment, is adequate and functioning properly. You must take appropriate corrective action as necessary.

(c) *Environmental monitoring*. You must monitor environmental conditions where environmental conditions could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable

disease agents. Where appropriate, you must provide environmental monitoring for microorganisms.

(d) *Records.* You must document, and maintain records of, environmental control and monitoring activities.

§ 1271.200 Equipment.

(a) *General.* To prevent the introduction, transmission, or spread of communicable diseases, equipment used in the manufacture of HCT/Ps must be of appropriate design for its use and must be suitably located and installed to facilitate operations, including cleaning and maintenance. Any automated, mechanical, electronic, or other equipment used for inspection, measuring, or testing in accordance with this part must be capable of producing valid results. You must clean, sanitize, and maintain equipment according to established schedules.

(b) *Procedures and schedules.* You must establish and maintain procedures for cleaning, sanitizing, and maintaining equipment to prevent malfunctions, contamination or cross-contamination, accidental exposure of HCT/Ps to communicable disease agents, and other events that could reasonably be expected to result in the introduction, transmission, or spread of communicable diseases.

(c) *Calibration of equipment.* Where appropriate, you must routinely calibrate according to established procedures and schedules all automated, mechanical, electronic, or other equipment used for inspection, measuring, and testing in accordance with this part.

(d) *Inspections.* You must routinely inspect equipment for cleanliness, sanitation, and calibration, and to ensure adherence to applicable equipment maintenance schedules.

(e) *Records.* You must document and maintain records of all equipment maintenance, cleaning, sanitizing, calibration, and other activities performed in accordance with this section. You must display records of recent maintenance, cleaning, sanitizing, calibration, and other activities on or near each piece of equipment, or make the records readily available to the individuals responsible for performing these activities and to the personnel using the equipment. You must maintain records of the use of each piece of equipment, including the identification of each HCT/P manufactured with that equipment.

§ 1271.210 Supplies and reagents.

(a) *Verification.* You must not use supplies and reagents until they have been verified to meet specifications designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases. Verification may be accomplished by the establishment that uses the supply or reagent, or by the vendor of the supply or reagent.

(b) *Reagents.* Reagents used in processing and preservation of HCT/Ps must be sterile, where appropriate.

(c) *In-house reagents.* You must validate and/or verify the processes used for production of in-house reagents.

(d) *Records.* You must maintain the following records pertaining to supplies and reagents:

(1) Records of the receipt of each supply or reagent, including the type, quantity, manufacturer, lot number, date of receipt, and expiration date;

(2) Records of the verification of each supply or reagent, including test results or, in the case of vendor verification, a certificate of analysis from the vendor; and

(3) Records of the lot of supply or reagent used in the manufacture of each HCT/P.

§ 1271.215 Recovery.

If you are an establishment that recovers HCT/Ps, you must recover each HCT/P in a way that does not cause contamination or cross-contamination during recovery, or otherwise increase the risk of the introduction, transmission, or spread of communicable disease through the use of the HCT/P.

§ 1271.220 Processing and process controls.

(a) *General.* If you are an establishment that processes HCT/Ps, you must process each HCT/P in a way that does not cause contamination or cross-contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P.

(b) *Pooling.* Human cells or tissue from two or more donors must not be pooled (placed in physical contact or mixed in a single receptacle) during manufacturing.

(c) *In-process control and testing.* You must ensure that specified requirements, consistent with paragraph (a) of this section, for in-process controls are met, and that each in-process HCT/P is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received and documented. Sampling of in-process HCT/Ps must be representative of the material to be evaluated.

(d) *Dura mater.* (1) When there is a published validated process that reduces the risk of transmissible spongiform encephalopathy, you must use this process for dura mater (or an equivalent process that you have validated), unless following this process adversely affects the clinical utility of the dura mater.

(2) When you use a published validated process, you must verify such a process in your establishment.

§ 1271.225 Process changes.

Any change to a process must be verified or validated in accordance with § 1271.230, to ensure that the change does not create an adverse impact elsewhere in the operation, and must be approved before implementation by a responsible person with appropriate knowledge and background. You must communicate approved changes to the appropriate personnel in a timely manner.

§ 1271.230 Process validation.

(a) *General.* Where the results of processing described in § 1271.220 cannot be fully verified by subsequent inspection and tests, you must validate and approve the process according to established procedures. The validation activities and results must be documented, including the date and signature of the individual(s) approving the validation.

(b) *Written representation.* Any written representation that your processing methods reduce the risk of transmission of communicable disease by an HCT/P, including but not limited to, a representation of sterility or pathogen inactivation of an HCT/P, must be based on a fully verified or validated process.

(c) *Changes.* When changes to a validated process subject to paragraph (a) of this section occur, you must review and evaluate the process and perform revalidation where appropriate. You must document these activities.

§ 1271.250 Labeling controls.

(a) *General.* You must establish and maintain procedures to control the labeling of HCT/Ps. You must design these procedures to ensure proper HCT/P identification and to prevent mix-ups.

(b) *Verification.* Procedures must include verification of label accuracy, legibility, and integrity.

(c) *Labeling requirements.* Procedures must ensure that each HCT/P is labeled in accordance with all applicable labeling requirements, including those in §§ 1271.55, 1271.60, 1271.65,

1271.90, 1271.290, and 1271.370, and that each HCT/P made available for distribution is accompanied by documentation of the donor eligibility determination as required under § 1271.55.

§ 1271.260 Storage.

(a) *Control of storage areas*. You must control your storage areas and stock rooms to prevent:

(1) Mix-ups, contamination, and cross-contamination of HCT/Ps, supplies, and reagents, and

(2) An HCT/P from being improperly made available for distribution.

(b) *Temperature*. You must store HCT/Ps at an appropriate temperature.

(c) *Expiration date*. Where appropriate, you must assign an expiration date to each HCT/P based on the following factors:

(1) HCT/P type;

(2) Processing, including the method of preservation;

(3) Storage conditions; and

(4) Packaging.

(d) *Corrective action*. You must take and document corrective action whenever proper storage conditions are not met.

(e) *Acceptable temperature limits*. You must establish acceptable temperature limits for storage of HCT/Ps at each step of the manufacturing process to inhibit the growth of infectious agents. You must maintain and record storage temperatures for HCT/Ps. You must periodically review recorded temperatures to ensure that temperatures have been within acceptable limits.

§ 1271.265 Receipt, predistribution shipment, and distribution of an HCT/P.

(a) *Receipt*. You must evaluate each incoming HCT/P for the presence and significance of microorganisms and inspect for damage and contamination. You must determine whether to accept, reject, or place in quarantine each incoming HCT/P, based upon pre-established criteria designed to prevent communicable disease transmission.

(b) *Predistribution shipment*. If you ship an HCT/P within your establishment or between establishments (e.g., procurer to processor) and the HCT/P is not available for distribution as described in paragraph (c) of this section, you must first determine and document whether pre-established criteria designed to prevent communicable disease transmission have been met, and you must ship the HCT/P in quarantine.

(c) *Availability for distribution*. (1) Before making an HCT/P available for distribution, you must review manufacturing and tracking records pertaining to the HCT/P, and, on the basis of that record review, you must verify and document that the release criteria have been met. A responsible person must document and date the determination that an HCT/P is available for distribution.

(2) You must not make available for distribution an HCT/P that is in quarantine, is contaminated, is recovered from a donor who has been determined to be ineligible or for whom a donor-eligibility determination has not been completed (except as provided under §§ 1271.60, 1271.65, and 1271.90), or that otherwise does not meet release criteria designed to prevent communicable disease transmission.

(3) You must not make available for distribution any HCT/P manufactured under a departure from a procedure relevant to preventing risks of communicable disease transmission, unless a responsible person has determined that the departure does not increase the risk of communicable disease through the use of the HCT/P. You must record and justify any departure from a procedure at the time of its occurrence.

(d) *Packaging and shipping*. Packaging and shipping containers must be designed and constructed to protect the HCT/P from contamination. For each type of HCT/P, you must establish appropriate shipping conditions to be maintained during transit.

(e) *Procedures*. You must establish and maintain procedures, including release criteria, for the activities in paragraphs (a) through (d) of this section. You must document these activities. Documentation must include:

(1) Identification of the HCT/P and the establishment that supplied the HCT/P;

(2) Activities performed and the results of each activity;

(3) Date(s) of activity;

(4) Quantity of HCT/P subject to the activity; and

(5) Disposition of the HCT/P (e.g., identity of consignee).

(f) *Return to inventory*. You must establish and maintain procedures to determine if an HCT/P that is returned to your establishment is suitable to be returned to inventory.

§ 1271.270 Records.

(a) *General*. You must maintain records concurrently with the performance of each step required in this subpart and subpart C of this part. Any requirement in this part that an action be documented involves the creation of a record, which is subject to the requirements of this section. All records must be accurate, indelible, and legible. The records must identify the person performing the work and the dates of the various entries, and must be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular HCT/P involved.

(b) *Records management system*. You must establish and maintain a records management system relating to core CGTP requirements. Under this system, records pertaining to a particular HCT/P must be maintained in such a way as to facilitate review of the HCT/Ps history before making it available for distribution and, if necessary, subsequent to the HCT/Ps release as part of a followup evaluation or investigation. Records pertinent to the manufacture of HCT/Ps (e.g., labeling and packaging procedures, and equipment logs) must also be maintained and organized under the records management system. If records are maintained in more than one location, then the records management system must be designed to ensure prompt identification, location, and retrieval of all records.

(c) *Methods of retention*. You may maintain records required under this subpart electronically, as original paper records, or as true copies such as photocopies, microfiche, or microfilm. Equipment that is necessary to make the records available and legible, such as computer and reader equipment, must be readily available. Records stored in electronic systems must be backed up.

(d) *Length of retention*. You must retain all records for 10 years after their creation, unless stated otherwise in this part. However, you must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/Ps distribution, disposition, or expiration, whichever is latest. You must retain records for archived specimens of dura mater for 10 years after the appropriate disposition of the specimens.

(e) *Contracts and agreements*. You must maintain the name and address and a list of the responsibilities of any establishment that performs a manufacturing step for you. This information must be available during an inspection conducted under § 1271.400.

§ 1271.290 Tracking.

(a) *General*. If you perform any step in the manufacture of an HCT/P in which you handle the HCT/P, you must track each such HCT/P in accordance with this section, to facilitate the

investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action.

(b) *System of HCT/P tracking.* (1) You must establish and maintain a system of HCT/P tracking that enables the tracking of all HCT/Ps from:

(i) The donor to the consignee or final disposition; and

(ii) The consignee or final disposition to the donor.

(2) Alternatively, if you are an establishment that performs some but not all of the steps in the manufacture of an HCT/P in which you handle the HCT/P, you may participate in a system of HCT/P tracking established and maintained by another establishment responsible for other steps in the manufacture of the same HCT/P, provided that the tracking system complies with all the requirements of this section.

(c) *Distinct identification code.* As part of your tracking system, you must ensure: That each HCT/P that you manufacture is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P; and that labeling includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor. Except in the case of autologous or directed donations, you must create such a code specifically for tracking, and it may not include an individual's name, social security number, or medical record number. You may adopt a distinct identification code assigned by another establishment engaged in the manufacturing process, or you may assign a new code. If you assign a new code to an HCT/P, you must establish and maintain procedures for relating the new code to the old code.

(d) *Tracking from consignee to donor.* As part of your tracking system, you must establish and maintain a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor.

(e) *Tracking from donor to consignee or final disposition.* As part of your tracking system, you must establish and maintain a method for documenting the disposition of each of your HCT/Ps, to enable tracking from the donor to the consignee or final disposition. The information you maintain must permit the prompt identification of the consignee of the HCT/P, if any.

(f) *Consignees.* At or before the time of distribution of an HCT/P to a consignee, you must inform the consignee in writing of the requirements in this section and of the tracking system that you have established and are maintaining to comply with these requirements.

(g) *Requirements specific to dura mater donors.* You must archive appropriate specimens from each donor of dura mater, under appropriate storage conditions, and for the appropriate duration, to enable testing of the archived material for evidence of transmissible spongiform encephalopathy, and to enable appropriate disposition of any affected nonadministered dura mater tissue, if necessary.

§ 1271.320 Complaint file.

(a) *Procedures.* You must establish and maintain procedures for the review, evaluation, and documentation of complaints as defined in §1271.3(aa), relating to core current good tissue practice (CGTP) requirements, and the investigation of complaints as appropriate.

(b) *Complaint file.* You must maintain a record of complaints that you receive in a file designated for complaints. The complaint file must contain sufficient information about each complaint for proper review and evaluation of the complaint (including the distinct identification code of the HCT/P that is the subject of the complaint) and for determining whether the complaint is an isolated event or represents a trend. You must make the complaint file available for review and copying upon request from FDA.

(c) *Review and evaluation of complaints.* You must review and evaluate each complaint relating to core CGTP requirements to determine if the complaint is related to an HCT/P deviation or to a adverse reaction, and to determine if a report under § 1271.350 or another applicable regulation is required. As soon as practical, you must review, evaluate, and investigate each complaint that represents an event required to be reported to FDA, as described in § 1271.350. You must review and evaluate a complaint relating to core CGTP requirements that does not represent an event required to be reported to determine whether an investigation is necessary; an investigation may include referring a copy of the complaint to another establishment that performed manufacturing steps pertinent to the complaint. When no investigation is made, you must maintain a record that includes the reason no investigation was made, and the name of the individual(s) responsible for the decision not to investigate.

■ 11. Part 1271 is amended by adding subpart E, consisting of §§ 1271.330 through 1271.370, to read as follows:

Subpart E—Additional Requirements for Establishments Described in § 1271.10

Sec.
1271.330 Applicability.
1271.350 Reporting.
1271.370 Labeling.

Subpart E—Additional Requirements for Establishments Described in § 1271.10

§ 1271.330 Applicability.

The provisions set forth in this subpart are being implemented for nonreproductive HCT/Ps described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and for the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the act, or are biological products regulated under section 351 of the Public Health Service Act, are not subject to the regulations set forth in this subpart.

§ 1271.350 Reporting.

(a) *Adverse reaction reports.* (1) You must investigate any adverse reaction involving a communicable disease related to an HCT/P that you made available for distribution. You must report to FDA an adverse reaction involving a communicable disease if it:

(i) Is fatal;

(ii) Is life-threatening;

(iii) Results in permanent impairment of a body function or permanent damage to body structure; or

(iv) Necessitates medical or surgical intervention, including hospitalization.

(2) You must submit each report on a Form FDA–3500A to the address in paragraph (a)(5) of this section within 15 calendar days of initial receipt of the information.

(3) You must, as soon as practical, investigate all adverse reactions that are the subject of these 15-day reports and must submit followup reports within 15 calendar days of the receipt of new information or as requested by FDA. If additional information is not obtainable, a followup report may be required that describes briefly the steps taken to seek additional information and the reasons why it could not be obtained.

(4) You may obtain copies of the reporting form (FDA–3500A) from the Center for Biologics Evaluation and Research (see address in paragraph (a)(5) of this section). Electronic Form

FDA–3500A may be obtained at *http://www.fda.gov/medwatch* or at *http://www.hhs.gov/forms*.

(5) You must submit two copies of each report described in this paragraph to the Center for Biologics Evaluation and Research (HFM–210), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. FDA may waive the requirement for the second copy in appropriate circumstances.

(b) *Reports of HCT/P deviations*. (1) You must investigate all HCT/P deviations related to a distributed HCT/P for which you performed a manufacturing step.

(2) You must report any such HCT/P deviation relating to the core CGTP requirements, if the HCT/P deviation occurred in your facility or in a facility that performed a manufacturing step for you under contract, agreement, or other arrangement. Each report must contain a description of the HCT/P deviation, information relevant to the event and the manufacture of the HCT/P involved, and information on all follow-up actions that have been or will be taken in response to the HCT/P deviation (e.g., recalls).

(3) You must report each such HCT/P deviation that relates to a core CGTP requirement on Form FDA–3486 available at *http://www.fda.gov/cber/biodev/bpdrform.pdf*, within 45 days of the discovery of the event either electronically at *http://www.fda.gov/cber/biodev/biodevsub.htm* or by mail to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (HFM–600), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

§ 1271.370 Labeling.

The following requirements apply in addition to §§ 1271.55, 1271.60, 1271.65, and 1271.90:

(a) You must label each HCT/P made available for distribution clearly and accurately.

(b) The following information must appear on the HCT/P label:

(1) Distinct identification code affixed to the HCT/P container, and assigned in accordance with § 1271.290(c);

(2) Description of the type of HCT/P;

(3) Expiration date, if any; and

(4) Warnings required under §§ 1271.60(d)(2), 1271,65(b)(2), or 1271.90(b), if applicable.

(c) The following information must either appear on the HCT/P label or accompany the HCT/P:

(1) Name and address of the establishment that determines that the HCT/P meets release criteria and makes the HCT/P available for distribution;

(2) Storage temperature;

(3) Other warnings, where appropriate; and

(4) Instructions for use when related to the prevention of the introduction, transmission, or spread of communicable diseases.

■ 12. Part 1271 is amended by adding subpart F, consisting of §§ 1271.390 through 1271.440, to read as follows:

Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10

Sec.

1271.390 Applicability.
1271.400 Inspections.
1271.420 HCT/Ps offered for import.
1271.440 Orders of retention, recall, destruction, and cessation of manufacturing.

Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10

§ 1271.390 Applicability.

The provisions set forth in this subpart are applicable only to HCT/Ps described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and to the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the act, or are biological products regulated under section 351 of the Public Health Service Act, are not subject to the regulations set forth in this subpart.

§ 1271.400 Inspections.

(a) If you are an establishment that manufactures HCT/Ps described in § 1271.10, whether or not under contract, you must permit the Food and Drug Administration (FDA) to inspect any manufacturing location at any reasonable time and in a reasonable manner to determine compliance with applicable provisions of this part. The inspection will be conducted as necessary in the judgment of the FDA and may include your establishment, facilities, equipment, finished and unfinished materials, containers, processes, HCT/Ps, procedures, labeling, records, files, papers, and controls required to be maintained under the part. The inspection may be made with or without prior notification and will ordinarily be made during regular business hours.

(b) The frequency of inspection will be at the agency's discretion.

(c) FDA will call upon the most responsible person available at the time of the inspection of the establishment and may question the personnel of the establishment as necessary to determine compliance with the provisions of this part.

(d) FDA's representatives may take samples, may review and copy any records required to be kept under this part, and may use other appropriate means to record evidence of observations during inspections conducted under this subpart.

(e) The public disclosure of records containing the name or other positive identification of donors or recipients of HCT/Ps will be handled in accordance with FDA's procedures on disclosure of information as set forth in parts 20 and 21 of this chapter.

§ 1271.420 HCT/Ps offered for import.

(a) Except as provided in paragraphs (c) and (d) of this section, when an HCT/P is offered for import, the importer of record must notify, either before or at the time of importation, the director of the district of the Food and Drug Administration (FDA) having jurisdiction over the port of entry through which the HCT/P is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part, and must provide sufficient information for FDA to make an admissibility decision.

(b) Except as provided in paragraphs (c) and (d) of this section, an HCT/P offered for import must be held intact by the importer or consignee, under conditions necessary to prevent transmission of communicable disease, until an admissibility decision is made by FDA. The HCT/P may be transported under quarantine to the consignee, while the FDA district reviews the documentation accompanying the HCT/P. When FDA makes a decision regarding the admissibility of the HCT/P, FDA will notify the importer of record.

(c) This section does not apply to reproductive HCT/Ps regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and donated by a sexually intimate partner of the recipient for reproductive use.

(d) This section does not apply to peripheral blood stem/progenitor cells regulated solely under section 361 of the Public Health Service Act and the regulations in this part, except that paragraphs (a) and (b) of this section apply when circumstances occur under which such imported peripheral blood stem/progenitor cells may present an unreasonable risk of communicable disease transmission which indicates the need to review the information referenced in paragraph (a) of this section.

§ 1271.440 Orders of retention, recall, destruction, and cessation of manufacturing.

(a) Upon an agency finding that there are reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of the regulations in this part and, therefore, the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission; or the HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or an establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission, the Food and Drug Administration (FDA) may take one or more of the following actions:

(1) Serve upon the person who distributed the HCT/P a written order that the HCT/P be recalled and/or destroyed, as appropriate, and upon persons in possession of the HCT/P that the HCT/P must be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the HCT/P is confirmed;

(2) Take possession of and/or destroy the violative HCT/P; or

(3) Serve upon the establishment an order to cease manufacturing until compliance with the regulations of this part has been achieved. When FDA determines there are reasonable grounds to believe there is a danger to health, such order will be effective immediately. In other situations, such order will be effective after one of the following events, whichever is later:

(i) Passage of 5 working days from the establishment's receipt of the order; or

(ii) If the establishment requests a hearing in accordance with paragraph (e) of this section and part 16 of this chapter, a decision in, and in accordance with, those proceedings.

(b) A written order issued under paragraph (a) of this section will state with particularity the facts that justify the order.

(c)(1) A written order issued under paragraph (a)(1) of this section will ordinarily provide that the HCT/P be recalled and/or destroyed within 5 working days from the date of receipt of the order. After receipt of an order issued under paragraph (a)(1) of this section, the establishment in possession of the HCT/P must not distribute or dispose of the HCT/P in any manner except to recall and/or destroy the HCT/P consistent with the provisions of the order, under the supervision of FDA.

(2) In lieu of paragraph (c)(1) of this section, other arrangements for assuring the proper disposition of the HCT/P may be agreed upon by the person receiving the written order and FDA. Such arrangements may include, among others, providing FDA with records or other written information that adequately ensure that the HCT/P has been recovered, processed, stored, and distributed in conformance with this part, and that, except as provided under §§ 1271.60, 1271.65, and 1271.90, the donor of the cells or tissue for the HCT/P has been determined to be eligible.

(d) A written order issued under paragraph (a)(3) of this section will specify the regulations with which you must achieve compliance and will ordinarily specify the particular operations covered by the order. After receipt of an order that is in effect and issued under paragraph (a)(3) of this section, you must not resume operations without prior written authorization of FDA.

(e) The recipient of an order issued under this section may request a hearing in accordance with part 16 of this chapter. To request a hearing, the recipient of the written order or prior possessor of such HCT/P must make the request within 5 working days of receipt of a written order for retention, recall, destruction, and/or cessation (or within 5 working days of the agency's possession of an HCT/P under paragraph (a)(2) of this section), in accordance with part 16 of this chapter. An order of destruction will be held in abeyance pending resolution of the hearing request. Upon request under part 16 of this chapter, FDA will provide an opportunity for an expedited hearing for an order of cessation that is not stayed by the Commissioner of Food and Drugs.

(f) FDA will not issue an order for the destruction of reproductive tissue under paragraph (a)(1) of this section, nor will it carry out such destruction itself under paragraph (a)(2) of this section.

Dated: June 17, 2004.

Lester Crawford,

Acting Commissioner of Food and Drugs.

Dated: September 16, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 04–25798 Filed 11–18–04; 12:30 pm]

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Part V

Federal Trade Commission

16 CFR Part 682

Disposal of Consumer Report Information and Records; Final Rule

FEDERAL TRADE COMMISSION

16 CFR Part 682

RIN 3084–AA94

Disposal of Consumer Report Information and Records

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Final rule.

SUMMARY: The Fair and Accurate Credit Transactions Act of 2003 (''FACT Act'' or ''Act'') requires the Federal Reserve Board, Office of the Comptroller of the Currency, Federal Deposit Insurance Corporation, Office of Thrift Supervision, National Credit Union Administration, Securities and Exchange Commission, and Federal Trade Commission, in coordination with one another, to adopt consistent and comparable rules regarding the proper disposal of consumer report information and records. This final rule implements this requirement.

DATES: This rule is effective on June 1, 2005.

FOR FURTHER INFORMATION CONTACT: Ellen Finn or Susan McDonald, Attorneys, (202) 326–3224, Division of Financial Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Statement of Basis and Purpose

I. Background

The Fair and Accurate Credit Transactions Act of 2003, Public Law 108–159, 117 Stat. 1952 (''FACT Act'' or ''Act'') was signed into law on December 4, 2003. In part, the Act amends the Fair Credit Reporting Act (''FCRA''), 15 U.S.C. 1681 *et seq.*, by imposing a new requirement on persons who possess or maintain, for a business purpose, consumer information derived from consumer reports. The Act requires that ''any person that maintains or otherwise possesses consumer information, or any compilation of consumer information, derived from consumer reports for a business purpose[,] properly dispose of any such information or compilation.'' [1]

The FACT Act directs the Commission to consult and coordinate with other agencies in connection with promulgating rules regarding the proper disposal of consumer report information and records. Specifically, the Act directs the Commission to consult and coordinate with the Federal banking agencies,[2] the National Credit Union Administration (''NCUA''), and the Securities and Exchange Commission (''SEC'') so that the regulations prescribed by each agency are consistent and comparable.[3] Further, the Act directs the Commission to ensure that the regulations are consistent with the requirements of the Gramm-Leach-Bliley Act (''GLBA''), 15 U.S.C. 6081 *et seq.*[4]

The Commission has conferred and coordinated extensively with the Federal banking agencies, the NCUA, and SEC to ensure that the agencies promulgate regulations that are comparable and consistent with each other and with the requirements of the GLBA.[5] On April 16, 2004, the Commission issued and sought comment on a proposed Rule implementing the requirements of section 216 of the FACT Act (the proposed Rule).[6] On July 8, 2004, the Commission supplemented its initial notice of proposed rulemaking (NPR), and sought comment on, a supplemental initial regulatory flexibility analysis (supplemental IRFA).[7] The supplemental IRFA was intended to provide additional information to assist small businesses in commenting on the impact, if any, the final Rule will have on such businesses. In response to both the NPR and the supplemental IRFA, the Commission received 58 comments from a variety of trade associations, businesses, consumer advocacy groups, and individuals. After carefully considering the comments received, the Commission adopts the proposed rule with only minor modifications described later in this notice.

Like the proposed rule, the final rule requires that persons over which the FTC has jurisdiction who maintain or otherwise possess consumer information for a business purpose properly dispose of such information by taking reasonable measures to protect against unauthorized access to or use of the information in connection with its disposal. It also includes several examples, including one new and two slightly revised examples, of what the Commission believes constitute reasonable measures to protect consumer information in connection with its disposal. These examples are intended to provide covered entities with guidance on how to comply with the rule but are not intended to be safe harbors or exclusive methods for complying with the rule.

In addition, the final rule maintains the flexible ''reasonable measures'' standard of the proposed rule. The FTC realizes that there are few foolproof methods of records destruction and that entities covered by the rule must consider their own unique circumstances when determining how to best comply with the rule.

Finally, the final rule extends the effective date of the rule from three months to six months following publication in the **Federal Register**.

II. Overview of Comments Received

The Commission received 58 comments on the proposed rule, five of which were in response to the supplemental IRFA.[8] The vast majority of these comments were from industry trade organizations [9] and the business community.[10] Consumer advocacy

[1] FACT Act section 216, 15 U.S.C. 1681w(a)(1).

[2] The Federal Reserve Board of Governors, Office of the Comptroller of the Currency, Federal Deposit Insurance Corporation, and Office of Thrift Supervision.

[3] 15 U.S.C. 1681w(a)(2)(A).

[4] 15 U.S.C. 1681w(a)(2)(B).

[5] The Federal banking agencies, NCUA, and SEC have proposed to implement § 216 of the FACT Act by amending their existing guidelines and rules on information security previously issued to implement section 501(b) of the GLBA. However, because the entities subject to the FTC's jurisdiction under the FACT Act and the GLBA are overlapping but not coextensive, the Commission has chosen to adopt a separate rule to implement § 216 of the FACT Act. Despite this difference in form, the substance of the rules is comparable and consistent.

[6] The notice of proposed rulemaking and proposed Rule were published in the **Federal Register** on April 20, 2004. 69 FR 21387.

[7] The supplemental IRFA was published in the **Federal Register** on July 8, 2004. 69 FR 41219.

[8] The public comments relating to this rulemaking may be viewed at *http://www.ftc.gov/os/comments/disposal/index.htm* (proposed Rule) and at *http://www.ftc.gov/os/comments/disposal-supplement/index.htm* (supplemental IRFA). The Commission considered all comments received on or before the close of the comment periods on June 15, 2004, for the proposed rule and on July 30, 2004, for the supplemental analysis. Citations to comments filed in this proceeding are made to the name of the organization (if any) or the last name of the commenter, and the comment number of record.

[9] These included the Consumer Data Industry Association (CDIA) (the trade association that represents the nationwide consumer reporting agencies and a variety of other consumer reporting agencies), the American Insurance Association, America's Community Bankers, ACA International (representing debt collection agencies and other accounts receivable professionals), ARMA International (the association of information management professionals), the National Association of Realtors, the Consumers Bankers Association, the Credit Union National Association (CUNA), the Michigan Credit Union League, the National Independent Automobile Dealer's Association, the Software & Information Industry Association (SIIA), the Pennsylvania Credit Union Association, the National Association of Profession Background Screeners, the National Association for Information Destruction, Inc. (NAID) (a trade association for the information destruction industry) and the Coalition to Implement the FACT Act (representing trade associations and companies that furnish, use, collect, and disclose consumer information).

[10] These included financial institutions, such as Bank of America Corporation, Countrywide Home

groups,[11] individual consumers, and one Senator[12] also submitted comments on the proposed rule.

The Commission received comments on nearly all of the provisions contained in the proposed rule. Most commenters, including consumers, businesses, and industry representatives, expressed general support for a rule requiring the proper disposal of consumer information. Many commenters noted that numerous companies that possess or maintain consumer report information already have programs in place to ensure the information's proper disposal, either as a matter of sound business practice or pursuant to other legal requirements. In general, commenters stated that they believed that the proposed rule would help combat fraud, such as identity theft. Indeed, some commenters urged the Commission to adopt provisions that extend beyond what the FACT Act provides in order to combat identity theft by, for example, expanding the scope of information covered under the rule to include payroll records and credit card receipts[13] or all information stored in the same file as consumer report information.[14]

The majority of commenters focused on the proposed rule's standard for disposal and definitions of ''consumer information'' and ''disposal.'' Most commenters expressed support for the proposed rule's ''reasonable measures'' standard for disposal. Commenters supporting the standard noted that its flexibility would allow covered persons to make decisions appropriate to their particular circumstances and that a more specific or uniform standard would be unrealistic, unnecessarily costly, and insufficiently flexible to deal with the broad range of entities subject to the final rule.[15] One consumer advocacy group stated that a more specific minimum standard is needed to ensure that all businesses implement adequate disposal practices;[16] another commenter suggested that the final rule should require covered persons to adopt formal, written information retention and disposal programs.[17]

In general, commenters also approved of the definitions of ''consumer information'' and ''disposal,''[18] but some suggested minor clarifications.[19] These comments are addressed more fully below.

In addition, the Commission received comments from industry representatives and financial institutions on the scope of the proposed rule. In general, these commenters stated that, for various reasons, consumer reporting agencies and other entities already subject to the Gramm-Leach-Bliley Act and the Commission's implementing Safeguards Rule[20] should not also be subject to the Disposal Rule.[21] Among other things, these commenters expressed concern that attempting to comply with multiple standards would engender uncertainty and possibly higher costs among persons covered by both rules. Commenters representing the records management and disposal industries[22] also expressed concern that the proposed rule would impose direct liability on such service providers for failing to properly dispose of records even when they have no contractual arrangements with the record owners requiring or paying them to do so. The Commission also received a comment from the U.S. Senator who introduced Section 216,[23] which stated that the scope of the proposed rule closely followed Congressional intent. These comments are addressed more fully below.

Overall, commenters were in favor of including examples of proper disposal methods in the final rule. Some commenters requested further clarification regarding the example involving garbage collectors.[24] Other commenters requested clarification as to whether the examples are minimum requirements, safe harbors, or simply illustrative guidance.[25] The Commission also received comments that discussed the effective date of the proposed rule. Numerous commenters requested that the period between issuance of the final rule and the effective date be lengthened.[26]

Finally, most commenters who addressed small business concerns stated that the proposed rule would not create any undue burden for small businesses. These commenters cited the proposed rule's flexible ''reasonable methods'' standard, which would allow covered persons to minimize costs, and the fact that the proposed rule would not impose new record keeping requirements, as the major factors that would alleviate any burdens on small businesses.[27]

III. Section-by-Section Analysis

Section 682.1: Definitions

Section 682.1(a) provides that, unless otherwise stated, terms used in the Disposal Rule have the same meaning as set forth in the Fair Credit Reporting Act, 15 U.S.C. 1681 *et seq.* Thus, for example, the term ''consumer report'' as used in the Disposal Rule has the same meaning as the term ''consumer report'' elsewhere in the FCRA. *See* 15 U.S.C. 1681a(d) (defining ''consumer report''). The Commission received no comments suggesting changes to this provision, and it is adopted as proposed.

Consumer Information

The proposed rule defined ''consumer information'' as any record about an individual, whether in paper, electronic, or other form, that is a consumer report or is derived from a consumer report. The NPR stated that the phrase ''derived from consumer reports'' would cover all

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Loans, Elgin Bank of Texas, MasterCard International Incorporated, MBNA America Bank, N.A., Virginia Credit Union, Inc. and Visa U.S.A.; credit reporting agencies, such as Equifax Information Services LLC, Experian Information Solutions, Inc., and Trans Union LLC; and information management and destruction firms, including AccuShred, LLC, Allshred Services, Inc., Community Shredders, IndyShred, PRISM International, Reclamere, Inc., SECURE Eco Shred, and Shred-it Orlando.

[11] These included Consumers Union and the Privacy Rights Clearinghouse, which was joined in its comments by Consumer Action, the Consumer Federation of California, the Identity Theft Resource Center, Privacy Activism, and the Worldwide Privacy Forum.

[12] Senator Bill Nelson (D–FL).

[13] *See* Comment, IndyShred #15

[14] *See* Comment, NAID #48.

[15] *See, e.g.*, Comment, Equal Employment Advisory Council #26; National Automobile Dealers Association #52; Comment, Mastercard #29; Comment, Equifax #54; Comment, Consumer Bankers Association #53; Comment, Coalition to Implement the FACT Act #64.

[16] *See*, Comment, Consumers Union #8; *see also* Comment, Gercken #14.

[17] *See* Comment, ARMA International #35.

[18] *See, e.g.*, Comment, CUNA #22; Comment, Visa U.S.A. #23 ; Comment, Consumer Bankers Association #53; Comment, CDIA #46.

[19] *See, e.g.*, Comment, CUNA #22; Comment, Equifax #54; Comment, Michigan Credit Union League #58; Comment, TransUnion #44; Comment, Mastercard #29; Comment, Consumer Bankers Association #53; Comment, Coalition to Implement the Fact Act #64; Comment, MBNA #19; Comment, Visa U.S.A. #23; Comment, American Financial Services Association #33; Comment, CDIA #46; Comment, Bank of America #51.

[20] 16 CFR part 314.

[21] *See, e.g.*, Comment, Experian #59; Comment, TransUnion #44; Comment, Mastercard #29; Comment, Equifax #54.

[22] *See, e.g.*, Comment, PRISM International #21; Comment, NAID #49.

[23] *See* Comment, Senator Bill Nelson #55.

[24] *See, e.g.*, Comment, CDIA #46; Comment, Equifax #54; Comment, NAID #49.

[25] *See, e.g.*, Comment, Mastercard #29; Comment, American Insurance Association #50.

[26] *See, e.g.*, Comment, Experian #59 (6 months); Comment, TransUnion #44 (6 months); Comment, Equifax #54 (6 months), Comment, American Financial Services Association #33 (6 months); Comment, American Insurance Association #50 (12 months); Consumer Bankers Association #53 (12 months); Comment, CDIA #46 (6 months); Comment, National Automobile Dealers Association #52 (9 months); Comment, Coalition to Implement the FACT Act #64 (6 months).

[27] *See, e.g.*, Comment, National Automobile Dealers Association #52; Comment, Mastercard #29; Comment, Consumer Bankers Association #53; Comment, Coalition to Implement the FACT Act #64.

of the information about a consumer that is derived from any consumer report(s), including information taken from a consumer report, information that results in whole or in part from manipulation of information taken from a consumer report, and information that has been combined with other types of information. Further, the NPR explained that because the definition of ''consumer information'' refers to records ''about an individual,'' information that does not identify particular consumers would not be covered under the rule. The Commission received a variety of comments requesting clarification or modification of this definition of consumer information.

One consumer advocacy group requested that the definition include compilations of consumer information.[28] Although the proposed rule already proposed to cover compilations of consumer information by referring to compilations in the scope and standard sections of the rule, the Commission agrees that it would be clearer to include compilations in the definition of consumer information itself. Therefore, it has modified the definition of consumer information to include compilations.

Commenters were uniformly supportive of the proposed rule's application only to information that identifies particular individuals,[29] but many requested that the rule be more explicit on this point.[30] In response to these comments, and in order to provide additional guidance and clarity, the Commission has added language to the rule emphasizing that information that does not identify individuals, such as aggregate information or blind data, is not covered by the definition of consumer information.[31]

Commenters also sought guidance on the kinds of information that would be considered to identify particular individuals.[32] The Commission believes that there are a variety of personal identifiers beyond simply a person's name that would bring information within the scope of the rule, including, but not limited to, a social security number, driver's license number, phone number, physical address, and e-mail address. The Commission has not included a rigid definition in the final rule, however, because, depending upon the circumstances, data elements that are not inherently identifying can, in combination, identify particular individuals.[33]

A number of commenters also requested that certain categories of information be excluded from the definition of consumer information. These include credit header information,[34] publicly available information,[35] and ''non-sensitive'' information.[36] Although credit header information, which includes name, address, and social security number, is not itself a consumer report, it is generally derived from a consumer report and, therefore, within the universe of information covered by section 216 of the FACT Act. Similarly, public record information is often part of consumer reports and therefore falls within the scope of information Congress intended to cover. With respect to ''non-sensitive'' information, the Commission notes that persons subject to the Disposal Rule may always consider the sensitivity of the consumer information at issue in determining what disposal measures are reasonable under the circumstances.

Finally, some commenters suggested that recipients of information about consumers may not always know whether the information they receive was derived from a consumer report.[37] They suggested, therefore, that the definition of ''consumer information'' be limited to information that a person knows to be derived from a consumer report.[38]

In response to these comments, the Commission notes that knowledge is not an element or a prerequisite to the duty to comply with either the FACT Act or the Disposal Rule. Nevertheless, the Commission also notes that in most, if not all, circumstances covered by the rule, covered entities will or should know if they possess consumer information. First, in most circumstances under the FCRA, a person who obtains a consumer report may use that information only for the specific permissible purpose for which it was obtained. In such circumstances, the person who possesses the information should clearly be aware that it is a consumer report.

Second, when consumer information is transferred to a service provider or shared between affiliates following consumer notice and opportunity to opt-out,[39] the Commission believes that, in light of the nature of the relationship and information sharing practices between such parties, service providers and affiliates generally will or should know when they have been provided with covered consumer information. Moreover, the Commission believes that, for persons subject to the rule, identifying consumer information when providing it to service providers or affiliates is one ''reasonable measure'' to ensure that the information will be disposed of properly in accordance with the rule.[40] For these reasons, the Commission has not modified the definition as requested by the comments.

Disposal

Proposed section 682.1(c) defined ''disposing'' or ''disposal'' to include the discarding or abandonment of consumer information, as well as the sale, donation, or transfer of any medium, including computer equipment, upon which consumer information is stored. The NPR noted that the sale, donation, or transfer of consumer information, by itself, would not be considered ''disposal'' under this definition.[41]

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[28] Comment, Consumers Union #8.

[29] *See, e.g.*, Comment, MBNA #19; Comment, Visa U.S.A. #23; Comment, Equal Employment Advisory Council #26; Comment, TransUnion #44; Comment, Mastercard #29; Comment, Equifax #54; Comment, American Financial Services Association #33; Comment, Consumer Bankers Association #53; Comment, CDIA #46; Comment, Bank of America #51; Comment, Coalition to Implement the Fact Act #64.

[30] *See, e.g.*, Comment, MBNA #19; Comment, Visa U.S.A. #23; Comment, TransUnion #44; Comment, Equifax #54; Comment, American Financial Services Association #33; Comment, CDIA #46; Comment, Bank of America #51.

[31] The terms ''aggregate information'' and ''blind data'' as used in the rule are intended to have the same meaning as in § 313.3(o)(2)(ii)(B) of the Commission's GLBA Rule regarding the Privacy of Consumer Financial Information, 16 CFR part 313.

[32] *See, e.g.*, Comment, Consumers Union #8; Comment, MBNA #19; Comment, Equifax #54; Comment, Senator Bill Nelson #55; Comment, Privacy Rights Clearinghouse #39; Comment, Michigan Credit Union League #58.

[33] *See* Comment, Consumers Union #8; Comment, Privacy Rights Clearinghouse #39.

[34] *See, e.g.*, Comment, Equifax #54.

[35] *See, e.g.*, Comment, National Independent Automobile Dealers Association #53.

[36] *See, e.g.*, Comment, America's Community Bankers #24; Comment, Mastercard #29.

[37] *See, e.g.*, Comment, Consumer Bankers Association #53; Comment, Coalition to Implement the Fact Act #64.

[38] *See, e.g.*, Comment, Mastercard #29; Comment, American Financial Services Association #33; Comment, Consumer Bankers Association #53; Comment, Coalition to Implement the Fact Act #64.

[39] *See* FCRA § 603(d)(2)(A)(iii), 15 U.S.C. 1681a(d)(2)(A)(iii).

[40] Example 3 of the final rule, which is discussed further below, illustrates this point as to service providers.

[41] A number of industry commenters requested an explicit statement to this effect in the rule. *See, e.g.*, Comment, America's Community Bankers #24; Comment, TransUnion #44; Comment, Mastercard #29; Comment, Consumer Bankers Association #53; Comment, NAID #49; Comment, Coalition to Implement the Fact Act #64. The Commission has not added such a statement to the final Rule because of its clear statement in the NPR, which it reaffirms here, that the sale, donation, or transfer of consumer information, by itself, does not constitute ''disposal'' under the Rule's definition. Of course, the FCRA's restrictions on the sale and use of

Some commenters suggested that the definition should state what disposal ''means'' as opposed to what it ''includes.''[42] The Commission agrees and has adopted this change in the final rule.

One commenter also suggested that the definition of disposal as ''the sale, donation, or transfer of any medium, including computer equipment, upon which consumer information is stored'' is not sufficiently broad with respect to the media and equipment covered.[43] This commenter suggested adding language specifically including computer media and other non-paper media and equipment. The Commission believes that the definition of disposal as proposed, which includes ''any medium * * * upon which consumer information is stored,'' is sufficiently broad to capture the materials of concern to the commenter.

Section 682.2: Purpose and Scope

Proposed section 682.2(a) set forth the purpose of the proposed Disposal Rule, which is to reduce the risk of consumer fraud and related harms, including identity theft, created by improper disposal of consumer information. The Commission received no comments suggesting changes to this provision, and it is adopted as proposed.

Proposed section 682.2(b), which tracks the language of section 216 of the FACT Act, sets forth the scope of the proposed Disposal Rule. The rule applies to ''any person over which the Federal Trade Commission has jurisdiction, that, for a business purpose, maintains or otherwise possesses consumer information, or any compilation of consumer information.'' The preamble to the proposed rule noted that the Commission reads ''for a business purpose'' broadly to include all business reasons for which a person may possess or maintain consumer information. As a result, the rule covers any person that possesses or maintains consumer information other than an individual consumer who has obtained his or her own consumer report or file disclosure.

As noted in the preamble to the proposed rule, among the entities that possess or maintain consumer information for a business purpose are consumer reporting agencies, as well as lenders, insurers, employers, landlords, government agencies, mortgage brokers, automobile dealers, and other users of consumer reports. In fact, all of the permissible purposes listed in § 604 of the FCRA would be considered business purposes under the rule.

The Commission received a number of financial industry comments arguing that the Disposal Rule should not apply to financial institutions subject to the Gramm-Leach-Bliley Act and the Commission's implementing Safeguards Rule.[44] These commenters' primary argument is that because the Safeguards Rule already covers information disposal, subjecting financial institutions to the Disposal Rule is unnecessary. Additionally, commenters expressed concern that attempting to comply with multiple standards would engender uncertainty and possibly higher costs among persons covered by both rules.

As the Commission stated in its Notice of Proposed Rulemaking, the coverage of the proposed Disposal Rule is different from that of the Commission's Safeguards Rule. In addition to covering a different (but overlapping) set of entities, the proposed Disposal Rule and the Safeguards Rule apply to different sets of information. *Compare* 16 CFR 314.1(b) (describing scope of ''customer information'' covered by Safeguards Rule) with Proposed Disposal Rule §§ 682.1(b) & 682.2(b) (defining scope of ''consumer information'' subject to proposed Disposal Rule).[45] As a result, the Commission believes that it is important to cover financial institutions under the Disposal Rule in order to ensure that the full range of information covered by section 216 of the FACT Act is properly protected in connection with its disposal. In addition, the plain language of section 216 of the FACT Act supports coverage of financial institutions.

In response to the commenters' concerns about the potential burdens imposed on persons covered by both the Safeguards Rule and Disposal Rule, the Commission notes that the substantive requirements of both rules are consistent with respect to disposal. Although the Safeguards Rule focuses on comprehensive information security and the Disposal Rule more narrowly on disposal, both incorporate flexible, risk-based standards that require reasonable measures to protect against unauthorized access to or use of information. As a result, compliance with the standards of the Disposal Rule will constitute compliance with the disposal obligations under the Safeguards Rule. Thus, companies should easily be able to develop approaches that satisfy the requirements of both rules without undue burdens or costs.[46] Accordingly, section 682.2(b) is adopted as proposed.

Section 682.3: Proper Disposal of Consumer Information

Under the proposed rule, any person that maintains or otherwise possesses consumer information would be required to ''take reasonable measures to protect against unauthorized access to or use of the information in connection with its disposal.'' Recognizing that there are few foolproof methods of record destruction, the NPR stated that the proposed rule would not require covered persons to ensure perfect destruction of consumer information in every instance; rather, it requires covered entities to take reasonable measures to protect against unauthorized access to or use of the information in connection with its disposal. In determining what measures are ''reasonable'' under the rule, the Commission stated in the NPR that it expects that entities covered by the rule would consider the sensitivity of the consumer information, the nature and size of the entity's operations, the costs and benefits of different disposal methods, and relevant technological changes. The Commission also noted that ''reasonable measures'' are very likely to require elements such as the establishment of policies and procedures governing disposal, as well as appropriate employee training.

The vast majority of commenters supported this flexible standard for disposal.[47] Commenters noted that the

consumer information are still applicable even when such information is sold, donated, or transferred in a manner that would not amount to ''disposal'' under this Rule.

[42] *See, e.g.*, Comment, TransUnion #44; Comment, Mastercard #29; Comment, Consumer Bankers Association #53; Comment, Coalition to Implement the Fact Act #64.

[43] *See* Comment, Consumers' Union #8.

[44] *See, e.g.* Comment, Experian #59; Comment, TransUnion #44; Comment, Mastercard #29; Comment, Equifax #54.

[45] For example, a consumer who applies for a loan from a financial institution, but is rejected based on information in her credit report is not a ''customer'' of the financial institution under the GLBA and her credit report would therefore not be protected by the Safeguards Rule; however, her credit report would be ''consumer information'' under the Disposal Rule. Credit reports obtained about employees or prospective employees are also not ''customer'' information covered under the GLBA, but would be ''consumer information'' under the Disposal Rule.

[46] Example 5 also illustrates that, for financial institutions subject to the Safeguards Rule, incorporation of the requirements of this rule into the information security program required by the Safeguards Rule constitutes compliance with this rule.

[47] *See, e.g.*, Comment, National Association of Professional Background Screeners #7; Comment, MBNA #19; Comment, Experian #59; Comment, CUNA #22; Comment, Visa U.S.A. #23; Comment, Equal Employment Advisory Council #26; Comment, TransUnion #44; Comment, National

Continued

standard will allow covered persons to make decisions appropriate to their particular circumstances;[48] minimize the costs of compliance, particularly for small businesses;[49] and harmonize the Disposal Rule with the requirements of the Commission's Safeguards Rule.[50] Accordingly, the basic standard for disposal has been adopted as proposed.

In order to provide additional clarity, the proposed rule also included examples intended to provide guidance on disposal measures that would be reasonable under the rule. Generally, commenters found the examples to be helpful. Although some commenters suggested treating the examples as minimum requirements,[51] many commenters approved of the examples remaining as illustrative guidance only and, in fact, requested a more explicit statement to that effect in the rule itself.[52] The Commission continues to believe that these examples should be illustrative only, not exhaustive, because they cannot take into account a particular entity's unique circumstances. In order to make this clear, the Commission has added language to the rule stating explicitly that ''These examples are illustrative only and are not exclusive or exhaustive methods for complying with this rule.''

Finally, commenters expressed concern that the final example, which addresses what would be ''reasonable measures'' for a disposal service provider or traditional garbage collector, is confusing with respect to the obligations of both service providers and the record owners who transfer consumer information to them.[53] In particular, commenters representing the records management and disposal industries pointed out that service providers are frequently not in a position to make independent determinations as to whether information they possess is, or was derived from, a consumer report.[54] In addition, these commenters argued that imposing direct liability for disposal on a service provider may allow, and even create incentives for, record owners to ''dump'' covered materials on service providers without paying for the proper destruction required by the rule.[55] These commenters suggest that service providers should be liable for violations of the rule only if the service provider (1) has been notified that the information it possesses is consumer information as defined in the rule; and (2) has entered into a written contract to dispose of such information in accordance with this rule.[56]

The Commission has addressed these commenters' concerns by revising the rule's examples to clarify what the ''reasonable measures'' standard requires when information is transferred or otherwise provided to service providers. First, the Commission has deleted the ''garbage collector'' example that caused some confusion. Second, the Commission has revised Example 3 so that it explicitly contemplates that a record owner would tell a service provider when it is providing the service provider with consumer information.[57] Thus, as revised, Example 3 illustrates that, if a record owner transfers or otherwise provides consumer information to a service provider, the ''reasonable measures'' standard will generally require a record owner to take reasonable steps to select and retain a service provider that is capable of properly disposing of the consumer information at issue; notify the service provider that such information is consumer information; and enter into a contract that requires the service provider to dispose of such information in accordance with this rule. This example clarifies record owners' responsibilities with respect to service providers while also ensuring that service providers have the information required, and make the arrangements needed, to fulfill their responsibilities under the rule. The Commission also notes that Example 3 harmonizes this aspect of the Disposal Rule with the Commission's GLBA Safeguards Rule which contains analogous requirements.

Under the final rule, service providers continue to be covered, and, therefore, along with the record owner, bear responsibility for proper disposal of consumer information that they maintain or otherwise possess. In evaluating a service provider's compliance with this rule, however, a record owner's failure to provide notice or contract for disposal in accordance with the requirements of the rule will be strongly considered. Other factors relevant to a service provider's liability and the ''reasonableness'' of its action include actual or constructive knowledge of the nature of the consumer information, the course of dealing between the service provider and record owner, and, consistent with the rule's overall ''reasonableness'' standard, the sensitivity of the consumer information, the nature and size of the service provider's operations, and the costs and benefits of different disposal methods.

The Commission also received a number of comments concerning the relationship between the Disposal Rule and Safeguards Rule. Many of these commenters requested an explicit statement in the rule that, for financial institutions subject to the Safeguards Rule, incorporation of the requirements of this rule into the information security program required by the Safeguards Rule constitutes compliance with this rule.[58] The Commission has added an Example 5 to illustrate this point.

Lastly, one commenter expressed concern that the phrase ''in connection with its disposal'' could be read to require reasonable measures to protect against unauthorized access or use of consumer information *during* the disposal process, but not following it.[59] The Commission intends the phrase ''in connection with its disposal'' to mean both during and after the disposal process.

Section 682.4: Relation to Other Laws

Proposed section 682.4(a) made clear that nothing in the rule is intended to create a requirement that a person maintain or destroy any record pertaining to a consumer. The proposed rule also stated that the rule is not intended to affect any requirement imposed under any other provision of law to maintain or destroy such records. The Commission received no comments

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Independent Automobile Dealers Association #53; Comment, Mastercard #29; Comment, Equifax #31; Comment, Consumer Bankers Association #53; Comment, CDIA #46; Comment, NAID #49; Comment, Bank of America #51; Comment, National Automobile Dealers Association #52; Comment, SIIA #56; Comment, Michigan Credit Union League #58; Comment, Coalition to Implement the FACT Act #64.

[48] *See, e.g.*, Comment, National Independent Automobile Dealers Association #53; Comment, Mastercard #29; Comment, Consumer Bankers Association #36; Comment, Coalition to Implement the FACT Act #64.

[49] *See, e.g.*, Comment, Equal Employment Advisory Council #26; Comment, Equifax #31.

[50] *See, e.g.*, Comment, MBNA #19; Comment, Visa U.S.A. #23; Comment, Coalition to Implement the FACT Act #64.

[51] *See, e.g.*, Comment, Consumers Union #8; Comment, NAID #49; Comment, Privacy Rights Clearinghouse #39.

[52] *See, e.g.*, Comment, CUNA #22; Comment, Mastercard #29; Comment, Countrywide Home Loans #43; Comment, Michigan Credit Union League #58.

[53] *See, e.g.*, Comment, CDIA #46; Comment, Equifax #54; Comment, NAID #49.

[54] Comment, PRISM International #21; Comment, NAID #49.

[55] Comment, PRISM International #21; Comment, NAID #49.

[56] Comment, PRISM International #21; Comment, NAID #49.

[57] Although the example involves a disposal service provider, the measures it contemplates would also generally be reasonable with respect to other types of services providers.

[58] *See, e.g.*, Comment, MBNA #19; Comment, America's Community Bankers #24; Comment, American Financial Services Association #33; Comment, Bank of America #51.

[59] Comment, Consumers Union #8.

suggesting changes to this provision, and it is adopted as proposed.

Section 682.5: Effective Date

The Commission initially proposed to make the Disposal Rule effective 3 months after the publication of the final rule. Although some commenters supported a 3-month effective date,[60] the majority of commenters requested a longer effective date in order to allow covered entities to develop and implement appropriate disposal procedures or to research and contract with service providers.[61] These commenters suggested time periods ranging from 6 to 12 months after the publication of the final rule. After considering the comments and balancing the need for protections against the need to allow covered entities sufficient time to come into compliance, the Commission has extended the effective date to be 6 months after publication of the final rule.

IV. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–612, requires that the Commission provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule and a Final Regulatory Flexibility Analysis (''FRFA''), with the final rule, unless the Commission certifies that the Rule will not have a significant economic impact on a substantial number of small business entities. For the majority of entities subject to the rule, a small business entity is defined by the Small Business Administration as one whose average annual receipts do not exceed $6 million or that has fewer than 500 employees.[62]

The Commission hereby certifies that the final rule will not have a significant economic impact on a substantial number of small business entities. The rule applies to ''any person that, for a business purpose, maintains or otherwise possesses consumer information, or any compilation of consumer information.'' As discussed in the NPR and in the supplemental IRFA, any company, regardless of industry or size, that possesses or maintains consumer information for a business purpose would be subject to the rule. Therefore, small entities across almost every industry could potentially be subject to the rule. However, as discussed in more detail below, many small entities subject to the rule are already subject to the GLBA Safeguards Rule,[63] which contains requirements similar to those in the rule. As a result, the marginal cost of compliance with the Disposal Rule for these businesses is likely to be minimal.

The Commission is unaware of any data concerning the frequency with which other small businesses obtain consumer reports. As a result, it is not possible to determine precisely how often small businesses would be required to undertake compliance efforts. In the July 8, 2004, supplemental IRFA, 69 FR 41219, the Commission asked several questions related to the existence, number, and nature of small business entities covered by the proposed rule, as well as the economic impact of the proposed rule on such entities. The Commission received five comments in response to its supplemental IRFA,[64] three of which addressed the small business issues raised. These comments, which are discussed in more detail below, were generally supportive of the rule as it applies to small businesses.[65]

The Commission continues to believe that a precise estimate of the number of small entities that fall under the rule is not currently feasible. However, based on the comments received and the Commission's own experience and knowledge of industry practices, the Commission also continues to believe that the cost and burden to small business entities complying with the rule is minimal and that the final rule will not have a significant impact on a substantial number of small entities. This document serves as notice to the Small Business Administration of the Commission's certification of no effect. Nonetheless, the Commission has decided to publish a Final Regulatory Flexibility Analysis with this final Rule. Therefore, the Commission has prepared the following analysis:

A. Need for and Objectives of the Rule

Section 216 of the FACT Act requires the Commission to issue regulations regarding the proper disposal of consumer information in order to prevent sensitive financial and personal information from falling into the hands of identity thieves or others who might use the information to victimize consumers. In this action, the Commission promulgates a final rule to fulfill the statutory mandate. The rule is authorized by and based upon section 216 of the FACT Act.

B. Significant Issues Raised by Public Comments.

On July 8, 2004, the Commission published a supplemental initial regulatory flexibility analysis for notice of proposed rulemaking, 69 FR 41219, in which the Commission asked several questions related to the existence, number, and nature of small business entities covered by the proposed rule, as well as the economic impact of the proposed rule on such entities. The Commission received five comments in response to its supplemental IRFA,[66] three of which addressed the small business issues raised.[67] These commenters all agreed that the rule should apply to small businesses. One commenter praised the proposed rule's reasonableness standard as ''provid[ing] ample flexibility for all covered entities, large and small.''[68] Another commenter cited the low cost of compliance.[69]

The Commission also received comments in response to the initial NPR that addressed small business concerns. These comments were also generally supportive of the proposed rule as it would apply to small businesses. Many commenters supported the purpose for promulgating the rule, and cited both the rule's flexible standard and the low costs of shredders and disposal services as evidence that the compliance costs to small businesses will be low.[70]

C. Small Entities to Which the Rule Will Apply

The Disposal Rule, which tracks the language of section 216 of the FACT Act, applies to ''any person that, for a business purpose, maintains or otherwise possesses consumer information, or any compilation of consumer information.'' The entities

[60] *See, e.g.*, Comment, CUNA #22.

[61] *See, e.g.*, Comment, Experian #59; Comment, TransUnion #44; Comment, National Independent Automobile Dealers Association #53; Comment, Equifax #54; Comment, American Financial Services Association #33; Comment, American Insurance Association #50; Consumer Bankers Association #53; Comment, CDIA #46; Comment, National Automobile Dealers Association #52; Comment, Coalition to Implement the FACT Act #64.

[62] 5 U.S.C. 603–605. These numbers represent the size standards for most retail and service industries ($6 million total receipts) and manufacturing industries (500 employees). A list of the SBA's size standards for all industries can be found at *http://www.sba.gov/size/summary-whatis.html.*

[63] 16 CFR part 314.

[64] Supplemental Comments were received from the NAID, the National Association of Realtors (NAR), the American Bankers' Association, ACRAnet, and an individual commenter.

[65] *See, e.g.*, Supp. Comment, NAID #6; Supp. Comment, Ms. Lisa Beavers #2; Supp. Comment, NAR #3.

[66] The NAID, the NAR, the American Bankers' Association, and two individual commenters.

[67] The other two comments raised issues already considered with respect to the rule generally.

[68] Supp. Comment, NAID #6.

[69] Supp. Comment, Beavers #2.

[70] Comment, Virginia Credit Union, Inc. #10; Comment, IndyShred #15; Comment, NAR #60; Comment, AccuShred, LLC #45.

covered by the rule would include consumer reporting agencies, resellers of consumer reports, lenders, insurers, employers, landlords, government agencies, mortgage brokers, automobile dealers, waste disposal companies, and any other business that possesses or maintains consumer information. As explained in the NPR and supplemental IRFA, any company, regardless of industry or size, that possesses or maintains consumer information for a business purpose will be subject to the rule. Therefore, numerous small entities across almost every industry could potentially be subject to the rule.

Although it is impossible to identify every industry that may possess or maintain consumer information [71] for business purposes, the Commission anticipates that, at a minimum, the small entities within the finance and insurance industries are likely to be subject to the rule. According to the Small Business Administration, there are approximately 231,000 small businesses within these industries.[72] Generally, these entities are already subject to the GLBA's Safeguards Rule, which contains requirements similar to those in the rule. As a result, as discussed further below, the marginal cost of compliance with the Disposal Rule for these businesses is likely to be minimal.

In addition, any business, regardless of industry, that obtains a consumer report, or information derived from a consumer report, will be subject to the rule. Among businesses that might fall into this category are landlords, utility companies, telecommunications companies, and any business that obtains consumer reports for employment screening purposes. The Commission is unaware of any data concerning the frequency with which small businesses such as these obtain consumer reports. As a result, it is not possible to determine precisely how many small businesses outside the finance and insurance industries will be subject to the rule, or how often these entities will be required to undertake compliance efforts.

D. Projected Reporting, Recordkeeping and Other Compliance Requirements

The final Disposal Rule does not impose any specific reporting, recordkeeping, or disclosure requirements within the meaning of the Paperwork Reduction Act. The rule requires covered entities, when disposing of consumer information, to take reasonable measures to protect against unauthorized access to or use of the information in connection with its disposal. What is considered ''reasonable'' will vary according to an entity's nature and size, the costs and benefits of available disposal methods, and the sensitivity of the information involved. In formulating the rule, the Commission considered alternatives to this approach, and determined that the flexibility afforded by the rule reduces the burden that might otherwise be imposed on small entities by a more rigid, prescriptive rule.

As noted above, entities already subject to the Commission's Safeguards Rule should incur few, if any, additional compliance costs. Among other things, the Safeguards Rule already requires covered entities to develop and implement policies that require the proper disposal of ''customer information'' (as defined in the GLBA), as well as employee training programs and mechanisms to update its information security program on a periodic basis. In light of these existing measures, modifying policies to address the disposal of ''consumer information'' (as defined in the rule), and training employees on these changes, should be possible at little or no cost. In fact, because the definitions of ''consumer information'' and ''customer information'' overlap, many entities may already be in substantial compliance with the rule's requirements.

For small businesses not already subject to the GLBA Safeguards Rule, compliance costs may be greater. Because the rule does not mandate specific disposal measures, a precise estimate of compliance costs is not feasible. However, there are certain basic steps that are likely to be appropriate for many small entities. For example, shredding or burning paper records containing consumer information will generally be appropriate. Depending upon the volume of records at issue and the office equipment available to the small entity, this method of disposal may be accomplished by the small entity itself at no cost, may require the purchase of a paper shredder (available at office supply stores for as little as $25), or may require the hiring of a document disposal service on a periodic basis (the costs of which will vary based on the volume of material, frequency of service, and geographic location).

If a small entity has stored consumer information on electronic media (for example, computer discs or hard drives), disposal of such media could be accomplished by a small entity at almost no cost by simply smashing the material with a hammer. In some cases, appropriate disposal of electronic media might also be accomplished by overwriting or ''wiping'' the data prior to disposal. Utilities to accomplish such wiping are widely available for under $25; indeed, some such tools are available for download on the Internet at no cost. Whether ''wiping,'' as opposed to destruction, of electronic media is reasonable, as well as the adequacy of particular utilities to accomplish that ''wiping,'' will depend upon the circumstances.

The Commission did not receive any information on the amount of employee time, measured in labor hours or costs, that might be incurred by compliance with the Disposal Rule. The Commission believes that all businesses, regardless of size, will need to educate and train their employees on proper disposal. The actual amount of time it will take to ensure that consumer report information is properly disposed will vary, depending on a variety of circumstances, including the amount and nature of covered records. However, the Commission believes many businesses may already be following industry best practices, which may include disposing of documents through shredders, using waste disposal companies, or other confidential disposal methods; and continuing to do so would not impose additional costs on such businesses.

As the above discussion illustrates, although it is not possible to estimate small businesses' compliance costs precisely, such costs are likely to be quite modest for most small entities.

E. Steps Taken To Minimize Significant Economic Impact of the Rule on Small Entities

The Commission considered whether to exempt any persons or classes of persons from the rule's application pursuant to section 216(a)(3) of the FACT Act. The FTC asked for comment on this issue, as well as any significant alternatives, consistent with the purposes of the FACT Act, that could further minimize the rule's impact on small entities. The Commission received no information or suggestions in response to this request; rather, commenters specifically voiced support for application of the rule to small businesses.[73]

[71] ''Consumer Information'' is defined in the proposed rule as any ''record about an individual, whether in paper, electronic, or other form, that is a consumer report or is derived from a consumer report.''

[72] This number represents 2001 totals as reported by the SBA. *See http://www.sba.gov/advo/stats/.*

[73] *See* Supp. Comment, NAID #6; Supp. Comment, Ms. Lisa Beavers #2; Supp. Comment, NAR #3.

The Commission also requested comment on the need to adopt a delayed effective date for small entities in order to provide them with additional time to come into compliance. The Commission received no comments on this issue; however, the Commission has decided to extend the effective date for all entities subject to the rule, from 3 months to 6 months following publication of this rule. This additional time will allow small entities to carefully assess their compliance obligations and make cost-sensitive decisions concerning how to best comply with the rule.

V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506 (PRA), the Commission reviewed the proposed and final rules. The rule explicitly provides that it is not intended ''(1) to require a person to maintain or destroy any record pertaining to a consumer that is not imposed under any other law; or (2) to alter or affect any requirement imposed under any other provision of law to maintain or destroy such a record.'' As such, the rule does not impose any recordkeeping requirement or otherwise constitute a ''collection of information'' as it is defined in the regulations implementing the PRA. *See* 5 CFR 1320.3(c).

VI. Final Rule

List of Subjects in 16 CFR Part 682

Consumer reports, Consumer reporting agencies, Credit, Fair Credit Reporting Act, Trade practices.

■ Accordingly, for the reasons stated in the preamble, the Federal Trade Commission amends 16 CFR chapter I, to add new part 682 as follows:

PART 682—DISPOSAL OF CONSUMER REPORT INFORMATION AND RECORDS

Sec.

682.1 Definitions.
682.2 Purpose and scope.
682.3 Proper disposal of consumer information.
682.4 Relation to other laws.
682.5 Effective date.

Authority: Pub. L. 108–159, sec. 216.

§ 682.1 Definitions.

(a) *In general.* Except as modified by this part or unless the context otherwise requires, the terms used in this part have the same meaning as set forth in the Fair Credit Reporting Act, 15 U.S.C. 1681 *et seq.*

(b) ''*Consumer information*'' means any record about an individual, whether in paper, electronic, or other form, that is a consumer report or is derived from a consumer report. Consumer information also means a compilation of such records. Consumer information does not include information that does not identify individuals, such as aggregate information or blind data.

(c) ''*Dispose,*'' ''*disposing,*'' or ''*disposal*'' means:

(1) The discarding or abandonment of consumer information, or

(2) The sale, donation, or transfer of any medium, including computer equipment, upon which consumer information is stored.

§ 682.2 Purpose and scope.

(a) *Purpose.* This part (''rule'') implements section 216 of the Fair and Accurate Credit Transactions Act of 2003, which is designed to reduce the risk of consumer fraud and related harms, including identity theft, created by improper disposal of consumer information.

(b) *Scope.* This rule applies to any person over which the Federal Trade Commission has jurisdiction, that, for a business purpose, maintains or otherwise possesses consumer information.

§ 682.3 Proper disposal of consumer information.

(a) *Standard.* Any person who maintains or otherwise possesses consumer information for a business purpose must properly dispose of such information by taking reasonable measures to protect against unauthorized access to or use of the information in connection with its disposal.

(b) *Examples.* Reasonable measures to protect against unauthorized access to or use of consumer information in connection with its disposal include the following examples. These examples are illustrative only and are not exclusive or exhaustive methods for complying with the rule in this part.

(1) Implementing and monitoring compliance with policies and procedures that require the burning, pulverizing, or shredding of papers containing consumer information so that the information cannot practicably be read or reconstructed.

(2) Implementing and monitoring compliance with policies and procedures that require the destruction or erasure of electronic media containing consumer information so that the information cannot practicably be read or reconstructed.

(3) After due diligence, entering into and monitoring compliance with a contract with another party engaged in the business of record destruction to dispose of material, specifically identified as consumer information, in a manner consistent with this rule. In this context, due diligence could include reviewing an independent audit of the disposal company's operations and/or its compliance with this rule, obtaining information about the disposal company from several references or other reliable sources, requiring that the disposal company be certified by a recognized trade association or similar third party, reviewing and evaluating the disposal company's information security policies or procedures, or taking other appropriate measures to determine the competency and integrity of the potential disposal company.

(4) For persons or entities who maintain or otherwise possess consumer information through their provision of services directly to a person subject to this part, implementing and monitoring compliance with policies and procedures that protect against unauthorized or unintentional disposal of consumer information, and disposing of such information in accordance with examples (b)(1) and (2) of this section.

(5) For persons subject to the Gramm-Leach-Bliley Act, 15 U.S.C. 6081 *et seq.*, and the Federal Trade Commission's Standards for Safeguarding Customer Information, 16 CFR part 314 (''Safeguards Rule''), incorporating the proper disposal of consumer information as required by this rule into the information security program required by the Safeguards Rule.

§ 682.4 Relation to other laws.

Nothing in the rule in this part shall be construed:

(a) To require a person to maintain or destroy any record pertaining to a consumer that is not imposed under other law; or

(b) To alter or affect any requirement imposed under any other provision of law to maintain or destroy such a record.

§ 682.5 Effective date.

The rule in this part is effective on June 1, 2005.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 04–25937 Filed 11–23–04; 8:45 am]

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Part VI

Department of Housing and Urban Development

List of Federally Assisted Programs; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4893–N–01]

List of Federally Assisted Programs

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice.

SUMMARY: This notice announces a list of HUD programs that are subject to the nondiscrimination provisions in Title VI of the Civil Rights Act of 1964.

FOR FURTHER INFORMATION CONTACT: Pamela Walsh, Director, Program Standards Division, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–2000, telephone (202) 708–2288, extension 7017 (this is not a toll-free number). Hearing- and speech-impaired individuals may access this telephone number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On September 11, 1995, HUD published a final rule (60 FR 47260) that removed from Title 24 of the Code of Federal Regulations any regulation determined unnecessary or obsolete. Among the numerous changes, HUD removed Appendix A from 24 CFR part 1. The regulations in 24 CFR part 1 effectuate the provisions of Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d–2000d–7), which provides that ''no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.'' Appendix A was a list of HUD's programs that provide Federal financial assistance and, therefore, are subject to the nondiscrimination provisions of Title VI and 24 CFR part 1.

In the September 11, 1995, final rule, HUD determined that Appendix A was unnecessary because no regulatory requirement is included and the information can be provided through other non-rulemaking means. To that end, HUD is publishing, and will publish periodically, a list of HUD programs that are subject to the provisions of Title VI. This notice is provided for information and reference; therefore applicability of Title VI and Title VI regulations is not affected by inclusion on or omission from this list.

HUD Programs Subject to Title VI

Community Planning and Development

1. *Community Development Block Grant (Entitlement Program),* Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*), 24 CFR part 570: Provides annual grants on a formula basis to entitled communities to carry out a wide range of community development activities directed toward neighborhood revitalization, economic development, and improved community facilities and services.

2. *Community Development Block Grant (State Program),* Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*), 24 CFR part 570: Provides annual grants on formal basis to carry out a wide range of community development activities directed toward neighborhood revitalization, economic development, and improved community facilities and services to states and units of local government in no-entitled areas.

3. *Community Development Block Grant (HUD-Administered Small Cities Program),* Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*), 24 CFR part 570: Provides annual grants on a formula basis to carry out a wide range of community development activities directed toward neighborhood revitalization, economic development, and improved community facilities and services. HUD's Honolulu Office administers the funds to non-entitled areas in the state of Hawaii (Kauai, Maui and Hawaii).

4. *Community Development Block Grant Section 108 Loan Guarantee Program,* Section 108 of the Housing and Community Development Act of 1974 (42 U.S.C. 5308), 24 CFR part 570, subpart M: Provides communities with a source of financing for economic development, housing rehabilitation, public facilities, and large-scale physical development projects.

5. *Community Development Block Grant (Disaster Recovery Assistance),* Title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*), Public Laws: 107–206, 107–117, 107–73, 107–38, 106–31, 105–277, 105–276, 105–174, 105–18, 104–134, 104–19, 103–327, 103–211, 103–75, and 103–50: Provides flexible grants to help cities, counties, and states recover from presidentially declared disasters, especially in low- and moderate-income areas.

6. *Community Development Block Grant—Section 107 (Insular Areas Grants),* Section 107, Housing and Community Development Act of 1974 (42 U.S.C. 5307), 24 CFR part 570: Provides annual grants on a formula basis to carry out a wide range of community development activities directed toward neighborhood revitalization, economic development, and improved community facilities and services. HUD's Honolulu and Caribbean field offices administer the funds to non-entitled areas in the insular areas of American Samoa, Guam, Northern Mariana Islands, and U.S. Virgin Islands.

7. *The HOME Investment Partnerships (HOME) Program,* Cranston-Gonzalez National Affordable Housing Act, Title II (1990) (42 U.S.C. 12701 *et seq.*), 24 CFR part 92: Provides grants to state and local governments to implement local housing strategies designed to increase homeownership and affordable housing opportunities for low- and very low-income Americans, including homeownership downpayment, tenant-based assistance, housing rehabilitation, assistance to homebuyers, and new construction of housing.

8. *Shelter Plus Care (S+C),* Cranston-Gonzales National Affordable Housing Act (Pub. L. 101–625), which amended Title IV of the McKinney-Vento Homeless Assistance Act by adding subtitle F authorizing the Shelter Plus Care Program, 24 CFR part 582: Provides rental assistance for homeless people with disabilities, primarily those with serious mental illness, chronic problems with alcohol or drugs or both, or acquired immunodeficiency syndrome (AIDS) and related diseases. Each dollar of rental assistance must be matched by dollar provided by the grantee from federal or private sources to be used for supportive services.

9. *Emergency Shelter Grants Program,* Title IV, McKinney-Vento Homeless Assistance Act (42 U.S.C. 11371–11378), as amended by Public Law 100–77, Public Law 101–625, Public Law 104–330, and Public Law 106–377, 24 CFR part 576: Provides grants to help increase the number and quality of emergency shelters for homeless individuals and families, to operate these facilities and provide essential supportive services, and to help prevent homelessness.

10. *Surplus Property for Use to Assist the Homeless,* Title V, McKinney-Vento Homeless Assistance Act, Section 501 of Title V, Public Law 101–645 (42 U.S.C. 11411), 24 CFR parts 581 and 586: Makes unutilized, underutilized, excess, or surplus Federal properties available to states, local governments, and nonprofit organizations for use to assist homeless persons.

11. *Supportive Housing Program—Transitional Housing Component,* Subtitle C of Title IV of the McKinney-

Vento Homeless Assistance Act (42 U.S.C. 11381): Provides grants for new construction, acquisition, rehabilitation, or leasing of buildings to house and provide supportive services to assist homeless persons to move into independent living; grants to fund a portion of annual operating costs and supportive services; and grants for technical assistance.

12. *Supportive Housing Program—Permanent Housing Component,* Subtitle C of Title IV of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11381), 24 CFR part 583: Provides grants for new construction, acquisition, rehabilitation, or leasing of buildings to develop community-based, long-term housing with support services for homeless persons with disabilities; grants to fund a portion of annual operating costs and supportive services; and grants for technical assistance.

13. *Section 8 Moderate Rehabilitation Single Room Occupancy (SRO) Program,* Title IV, subtitle E, McKinney-Vento Homeless Assistance Act (42 U.S.C. 11401), 24 CFR part 882, subpart H: Assists very low-income, single, homeless individuals in obtaining decent, safe, and sanitary housing in privately-owned rehabilitated buildings through Section 8 rental assistance payments to participating landlords.

14. *Brownfields Economic Development Initiative (BEDI),* Section 108(q) of the Housing and Community Development Act of 1974 (42 U.S.C. 5308(q)): Provides competitive economic development grants to CDBG recipients for enhancing either the security of guaranteed loans or the viability of projects financed under Section 108. Grants are used to redevelop industrial or commercial sites known as brownfields due to the presence or potential presence of environmental contamination.

15. *Economic Development Initiative (EDI) Grants,* Section 108(q) of the Housing and Community Development Act of 1974, as added by Section 232(a)(1) of the Multifamily Property Disposition Reform Act of 1994 (42 U.S.C. 5308(q)): Provides economic development grants to CDBG recipients for the purpose of enhancing either the security of guaranteed loans or the viability of projects financed by those loans. EDI enables localities to carry out eligible economic development activities, especially for low- and moderate-income persons, and reduce the risk of potential defaults on Section 108 loan guarantee-assisted projects.

16. *Round II Urban Empowerment Zones,* Provides grants for economic development activities in economically disadvantaged areas.

17. *Youthbuild,* Subtitle D of Title IV of the Cranston-Gonzales National Affordable Housing Act (42 U.S.C. 12899 *et seq.*), 24 CFR part 585: Provides economically disadvantaged young adults with opportunities to obtain education, employment skills, and meaningful on-site work experience and expands the supply of affordable housing for homeless and low- and very low-income persons.

18. *Rural Housing and Economic Development,* The ''Rural Housing and Economic Development'' heading in the appropriations acts for Fiscal Years 1999, 2000, 2001, 2002, and 2003: Provides grants to meet rural communities' economic and housing needs.

19. *Self-Help Homeownership Opportunity Program (SHOP),* Section 11 of the Housing Opportunity Program Extension Act of 1996 (42 U.S.C. 12805 note): Provides competitive grants to national and regional organizations and consortia that provide or facilitate self-help housing opportunities. Under the program, homebuyers and volunteers contribute a significant amount of sweat equity toward home construction.

20. *Capacity Building for Community Development,* Section 4 of the HUD Demonstration Act of 1993 (Pub. L. 103–120; 42 U.S.C. 9816 note, as amended by Section 10004 of Pub. L. 105–118): Provides grants to develop the capacity and ability of community development corporations and community housing development organizations to undertake community development and affordable housing projects and programs.

21. *Housing Opportunities for Persons With AIDS (HOPWA),* The AIDS Housing Opportunity Act (42 U.S.C. 12901 *et seq.*), Subtitle D of Title VIII of the Cranston-Gonzalez National Affordable Housing Act, 24 CFR part 574: Provides grants to eligible states and cities to provide housing assistance and related supportive services to meet the needs of low-income persons with HIV/AIDS or related diseases and their families.

22. *Neighborhood Initiatives Program,* The appropriations acts for Fiscal Years 1998, 1999, 2000, 2001, 2002, and 2003: Provides funding for neighborhood initiatives that improve the conditions of distressed and blighted areas and neighborhoods; to stimulate investment, economic diversification, and community revitalization in areas with population outmigration or a stagnating or declining economic base; or to determine whether housing benefits can be integrated more effectively with welfare reform initiatives.

23. *Technical Assistance Programs—HOME, CHDO (HOME), McKinney-Vento Homeless Assistance, and HOPWA:* Funds are available to provide technical assistance, under cooperative agreements with HUD, for four separate programs: (1) HOME Investment Partnerships Program; (2) HOME Investment Partnerships Program for Community Housing Development Organizations; (3) McKinney-Vento Homeless Assistance; and (4) Housing Opportunities for Persons with AIDS (HOPWA).

Single Family Housing Programs

24. *Single Family Property Disposition (204(g)),* Section 203, National Housing Act (12 U.S.C. 1709(b)), 24 CFR part 203: Disposes of one-to four-family FHA properties, either through the competitive, sealed-bid process or direct sale, and constitutes Federal financial assistance where such sales are to nonprofit organizations, states, or local governments and are discounted below fair market value.

25. *Counseling for Homebuyers, Homeowners, and Tenants (Section 106),* Section 106, Housing and Urban Development Act of 1968 (12 U.S.C. 1701x): Awards housing counseling grants on a competitive basis to approved counseling agencies.

Multifamily Housing Programs

26. *Supportive Housing for the Elderly (Section 202),* Section 202, Housing Act of 1959 (12 U.S.C. 1701q), as amended by Section 801 of the Cranston-Gonzalez National Affordable Housing Act, 24 CFR part 891: Provides interest-free capital advances to eligible private, nonprofit organizations to finance the development of rental housing with supportive services for the elderly. In addition, project rental assistance contract (PRAC) funds are used to cover the difference between the tenants' contributions toward rent and the HUD-approved expense to operate the project. PRAC funds may also be used to provide supportive services and to hire a service coordinator in projects serving frail elderly residents.

27. *Assisted Living Conversion Program (ALCP),* Section 202(b), Housing Act of 1959 (12 U.S.C. 1701q): Provides grants to private, nonprofit owners of eligible developments to convert some or all of the dwelling units in the development into an assisted living facility for the frail elderly.

28. *Multifamily Housing Service Coordinators,* Section 808, Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 8012), as amended by the Housing and Community Development Act of 1992 (Pub. L. 102–550) and the American Homeownership and Economic Opportunity Act of 2000

(Pub. L. 106–569): Provides funding for service coordinators that assist elderly individuals and persons with disabilities who live in federally assisted multifamily housing to obtain needed supportive services from community agencies.

29. *Supportive Housing for Persons with Disabilities (Section 811),* Section 811, Cranston-Gonzalez National Affordable Housing Act, 24 CFR part 891: Provides interest-free capital advances to eligible nonprofit sponsors to finance the development of rental housing with the availability of supportive services for persons with disabilities. PRAC funds are used to cover the difference between the tenants' contributions toward rent and the HUD-approved cost to operate the project.

30. *Self-Help Housing Property Disposition,* Public Law 105–50; approved October 6, 1997: Makes surplus federal properties available through sale at less than fair market value to states, their subdivisions and instrumentalities, and nonprofit organizations for self-help housing for low-income persons. Residents of the property make a substantial contribution of labor toward the construction, rehabilitation, or refurbishment of the property.

31. *Mark to Market: Outreach and Training Assistance,* Multifamily Assistance and Housing Reform and Affordability Act of 1997 (42 U.S.C. 1437f note), 24 CFR parts 401 and 402: Provides funding for technical assistance for tenant groups in properties with project-based rental assistance contracts that are nearing expiration and properties whose tenants have been notified that the owner intends to prepay its HUD-insured mortgage. The funding supports outreach, organizing, and training activities for tenants in units receiving HUD assistance.

Public and Indian Housing

32. *Housing Choice Voucher Program,* Section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f), Section 8(o) for vouchers (tenant-based and project-based) and Section 8(t) for enhanced vouchers, 24 CFR part 5 (certain cross-cutting requirements); 24 CFR part 982, Tenant-based Housing Choice Voucher Program; 24 CFR part 983, Project-based Voucher Program; 24 CFR part 984, Section 8 Family Self-Sufficiency Program; and 24 CFR part 985, Section 8 Management Assessment Program (SEMAP): Provides tenant-based housing assistance subsidies for units that are (in general) chosen by the tenant in the private market.

33. *Mainstream Program.* Consolidated Appropriations Act, 2004 (Pub. L. 108–199, approved January 23, 2004): Provides tenant-based housing assistance for persons with disabilities living in units chosen by the tenant in the private market.

34. *Housing Voucher Homeownership Assistance,* Section 8(y) of the United States Housing Act of 1937, Section 302 of the American Homeownership and Economic Opportunity Act of 2000 (Pub. L. 106–569), 24 CFR part 982, subpart M: Provides monthly assistance to families who are current voucher participants and are purchasing homes in an amount that otherwise would have been provided to that family as tenant-based voucher assistance.

35. *Project-Based Voucher Program,* Section 8(o)(13) of the United States Housing Act of 1937 (42 U.S.C. 1473f(o)(13)), as amended by Section 232 of the Fiscal Year 2001 appropriations act (Pub. L. 106–377, approved October 27, 2000), 66 FR 3605—Regulations will be codified at 24 CFR part 983: Provides rental assistance for eligible families who live in specific housing developments or units.

36. *Renewal of Section 8 Project-Based Rental Assistance:* Assists low- and very low-income families in obtaining decent, safe, and sanitary housing in private accommodations. Rental assistance was originally used in conjunction with both existing properties and new construction (Section 8 New Construction/ Substantial Rehabilitation, and Loan Management and Property Disposition Set Aside programs). Funding no longer is available for new commitments beyond renewing expiring contracts on units already receiving project-based Section 8 rental assistance.

37. *Public Housing Operating Fund,* Section 9(e) of the United States Housing Act of 1937 (42 U.S.C. 1437g(e)), 24 CFR part 990: Provides an annual subsidy to public housing agencies (PHAs) for operations and management.

38. *Public Housing Capital Fund,* Section 9 of the United States Housing Act of 1937 (42 U.S.C. 1437g(d)), 24 CFR parts 905 and 968: Provides capital and management funding for PHAs.

39. *Public Housing/Section 8 Moving to Work,* Section 204 of the Fiscal Year 1996 Appropriations Act (Pub. L. 104–134), and Section 599H(e) of the Quality Housing and Work Responsibility Act (Pub. L. 105–276): Provides incentives to PHAs to design and test approaches for providing and administering housing assistance that save money, give incentives to families with children to become economically self-sufficient, and increase housing choices for low-income families; also provides training and technical assistance to identify replicable program models.

40. *Demolition and Revitalization of Severely Distressed Public Housing (HOPE VI),* appropriations acts for Fiscal Year 1993 through 1999; Section 24 of the United States Housing Act of 1937, as amended by Section 535 of the Quality Housing and Work Responsibility Act of 1998 (42 U.S.C. 1437v): Provides competitive grants to PHAs to eradicate severely distressed public housing through demolition, major reconstruction, rehabilitation, and other physical improvements; the provision of replacement housing; management improvements; planning and technical assistance; and the provision of supportive services.

41. *Public Housing Homeownership—Section 32,* Section 32 of the United States Housing Act of 1937 (42 U.S.C. 1437z–4), 24 CFR part 906: Sells public housing units to low-income families.

42. *Resident Opportunity and Self Sufficiency (ROSS),* Section 34 of the United States Housing Act of 1937 (42 U.S.C. 1437z–6), as amended by Section 221 of the Fiscal Year 2001 Appropriations Act: Provides grants to PHAs for supportive services and resident empowerment activities.

43. *Family Self-Sufficiency Program,* Section 23 of the United States Housing Act of 1937 (42 U.SA.C. 1437u), 24 CFR 984: Promotes the development of local strategies to coordinate the use of public housing and Housing Choice Voucher program assistance with public and private resources to enable eligible families to achieve economic independence and self-sufficiency.

44. *Indian Housing Block Grant (IHBG) Program,* Titles I–V of the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA) (25 U.S.C. 4101 *et seq.*), 24 CFR part 1000: Provides housing assistance under a single block grant to eligible Indian tribes or their tribally designated housing entities. Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) and Title VIII of the Civil Rights Act of 1968 (42 U.S.C. 3601 *et seq.*) apply to Indian tribes that are not covered by the Indian Civil Rights Act. **Note:** the Title VI and Title VIII nondiscriminatory requirements do not apply to actions by Indian tribes under Section 201(b) of the Native American Housing Assistance and Self-Determination Act of 1996.

45. *Native Hawaiian Housing Block Grant (NHHBG) Program,* Title VIII of NAHASDA, as added by Section 513 of the American Homeownership and Economic Opportunity Act of 2000 (Pub. L. 106–569) and Section 203 of the

Omnibus Indian Advancement Act (Pub. L. 106–568): Provides block grants to address the housing needs and circumstances of Native Hawaiians.

Fair Housing and Equal Opportunity

46. *Fair Housing Initiatives Program (FHIP),* Section 561, Housing and Community Development Act of 1987 (42 U.S.C. 3616(a)), 24 CFR part 125: Provides funding to private not-for-profit and for-profit fair housing organizations and Fair Housing Assistance Program (FHAP) agencies for carrying out educational and enforcement programs to prevent or eliminate discriminatory housing practices.

Policy Development and Research

47. *Doctoral Research Grant Programs,* Title V of the Housing and Urban Development Act of 1970 (12 U.S.C. 1701z–1 *et seq.*): Provides competitive grants to Ph.D. candidates to enable them to complete their dissertations, to Ph.D. students early in their studies to complete research projects, and to Ph.D.s early in their academic careers to undertake research on issues related to HUD's priorities.

48. *Bridges to Work,* Supportive services program authorized under the CDBG heading in the Fiscal Year 1996 appropriations act (Pub. L. 104–134): Provides grants to link low-income, inner-city residents with suburban jobs by providing job placement, transportation, and supportive services, such as child care and counseling.

49. *Research on Socioeconomic Change in Cities:* Provides grants to academic institutions, nonprofit organizations, and municipalities for research dealing with trends in urban areas, including social, economic, demographic, and fiscal changes.

50. *Community Outreach Partnership Program (COPC),* Section 107, Housing and Community Development Act of 1974 (42 U.S.C. 5307), 24 CFR part 570: Assists in establishing or implementing outreach and applied research activities that address problems of urban areas and encourages structural change, both within institutions of higher education and in the way institutions relate to their neighbors.

51. *Historically Black Colleges and Universities Program (HBCU),* Section 107, Housing and Community Development Act of 1974 (42 U.S.C. 5307), 24 CFR part 570: Assists HBCUs in expanding their role and effectiveness in addressing community development needs in their localities, including neighborhood revitalization, housing, and economic development, principally for persons of low and moderate income.

52. *Hispanic-Serving Institutions Assisting Communities Program (HSIAC),* Consolidated Appropriations Act, 2004 (Pub. L. 108–199, approved January 23, 2004): Provides grants to assist Hispanic-serving institutions in expanding their role and effectiveness in addressing community development needs in their localities, including neighborhood revitalization, housing, and economic development.

53. *Alaska Native/Native Hawaiian Institutions Assisting Communities Program (AN/NHIAC),* Consolidated Appropriations Act, 2004 (Pub. L. 108–199, approved January 23, 2004): Assists Alaska Native/Native Hawaiian Institutions of higher education in expanding their role and effectiveness in addressing community development needs in their localities, including neighborhood revitalization, housing, and economic development, principally for persons of low and moderate income.

54. *Tribal Colleges and Universities Program (TCUP),* Consolidated Appropriations Act, 2004 (Pub. L. 108–199, approved January 23, 2004): Assists tribal colleges and universities in building, expanding, renovating, and equipping their own facilities. Title VI applies only to tribal colleges and universities that are not a part or instrumentality of a tribe.

Healthy Homes and Lead Hazard Control

55. *Lead Hazard Control,* Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4821 *et seq.*), Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X of the Housing and Community Development Act of 1992, 42 U.S.C. 4851 *et seq.*), Sections 501 and 502 of the Housing and Urban Development Act of 1970 (12 U.S.C. 1701z–1 and 1701z–2), 24 CFR part 35: Provides grants to state and local governments to evaluate and reduce lead-based paint hazards in privately owned, low-income housing and to nonprofit and for-profit entities to leverage private sector resources to eliminate lead poisoning as a major public health threat to children.

56. *Lead-based Paint Hazard Control Program,* Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4821 *et seq.*), Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X of the Housing and Community Development Act of 1992, 42 U.S.C. 4851 *et seq.*), Sections 501 and 502 of the Housing and Urban Development Act of 1970 (12 U.S.C. 1701z–1 and 1701z–2), 24 CFR part 35: Provides grants to government entities that will formally partner with faith-based and community organizations to reduce lead hazards in eligible privately owned rental and owner-occupied housing

57. *Healthy Homes Demonstration Program,* Sections 501 and 502 of the Housing and Urban Development Act of 1970 (12 U.S.C. 1701z–1 and 1701z–2): Provides grants to state and local governments, federally recognized Indian tribes, and nonprofit applicants for controlling a variety of environmentally unhealthy housing conditions, especially for children.

58. *Operation Lead Elimination Action Program (LEAP),* Consolidated Appropriations Act, 2004 (Pub. L. 108–199, approved January 23, 2004): Provides grants to nonprofit and for-profit organizations and universities that can leverage HUD funds with private resources and who will reallocate resources to other entities to eliminate lead in residential buildings, especially for low-income, privately owned or owner-occupied housing.

59. *Lead Outreach Grant Program,* Sections 1011(e)(8) and (g)(1) of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X of the Housing and Community Development Act of 1992), Consolidated Appropriations Resolution of 2004, Public Law 108–199, approved January 23, 2004): Provides funding to nonprofit and for-profit organizations to develop and distribute outreach and educational materials.

60. *Healthy Homes and Lead Technical Studies,* Sections 501 and 502 of the Housing and Urban Development Act of 1970 (12 U.S.C. 1701z–1 and 1701z–2), Consolidated Appropriations Act, 2004 (Pub. L. 108–199, approved January 23, 2004): Funds research to find improved methods for detecting and controlling lead-based paint and other residential health and safety hazards.

Inactive HUD Programs

(Programs With No New Funding, But That May Still Fund Previous Contracts)

61. *Rent Supplements:* Provided federal payments to reduce rents for certain low-income persons. New rent supplement contracts are no longer available.

62. *Congregate Housing Services:* Provided federal grants to eligible housing projects for the elderly and disabled. No activity in recent years except to extend previously funded grants.

63. *HOPE 2 Homeownership of Multifamily Units:* Provided grants to assist in developing and carrying out

homeownership programs for low-income families and individuals through the use of multifamily rental properties. No new commitments are being made.

64. *HOPE for Homeownership of Single Family Homes (HOPE 3) Program:* Provided grants to assist in developing and carrying out homeownership programs for low-income families and individuals through the rehabilitation of existing single-family homes. No new commitments since 1995.

65. *Emergency Low-Income Housing Preservation (Title II) (except for FHA-mortgage insurance):* Addressed the preservation of Section 221(d)(3) and Section 236 projects whose low-income use restrictions could otherwise expire 20 years after the final mortgage endorsement. No new commitments are being made.

66. *Low-Income Housing Preservation and Resident Homeownership (Title VI) (except for FHA-mortgage insurance):* Addressed the preservation of Section 221(d)(3) and Section 236 projects whose low-income use restrictions could otherwise expire 20 years after the final mortgage endorsement. No new commitments are being made.

67. *Flexible Subsidy (Section 201):* Provided federal aid for troubled multifamily housing projects as well as capital improvement funds for both troubled and stable subsidized projects. No new commitments are being made.

68. *Direct Loans for Housing for the Elderly or Handicapped (Section 202):* Provided housing and related facilities for the elderly or handicapped. This program was replaced in Fiscal Year 1999 by the Supporting Housing Program for the Elderly (Section 202 Capital Advances) and Housing for Persons with Disabilities (Section 811).

69. *Section 8 Moderate Rehabilitation Program:* Assisted very low-income families in obtaining decent, safe, and sanitary housing in privately owned, rehabilitated buildings. Funding is no longer available for new commitments beyond renewing expiring contracts.

70. *Section 8 Welfare to Work:* Provided rent assistance for families moving from welfare dependency to self-sufficiency. No funding has been appropriated since Fiscal Year 1999.

71. *Homeownership and Opportunity for People Everywhere (HOPE I):* Made available grants to provide affordable homeownership to the residents of public housing. No funding has been appropriated since Fiscal Year 1995.

72. *Moving to Opportunity for Fair Housing:* Assisted certain low-income families with children to move to areas of low concentrations of persons living in poverty. No funding has been appropriated since Fiscal Year 1992.

73. *Regional Opportunity Counseling Programs:* Provided funds to PHAs that partner with other PHAs and nonprofit organizations to provide counseling to holders of tenant-based vouchers to help them understand the benefits of de-concentrated areas.

74. *Public and Indian Housing Drug Elimination Program:* Grants to fund drug elimination activities in public, assisted, and Indian housing.

Dated: November 18, 2004.

Carolyn Peoples,

Assistant Secretary for Fair Housing and Equal Opportunity.

[FR Doc. 04–25986 Filed 11–23–04; 8:45 am]

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Federal Register

Wednesday,
November 24, 2004

Part VII

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Updating OSHA Standards Based on National Consensus Standards; General, Incorporation by Reference; Hazardous Materials, Flammable and Combustible Liquids; General Environmental Controls, Temporary Labor Camps; Hand and Portable Powered Tools and Other Hand Held Equipment, Guarding of Portable Powered Tools; Welding, Cutting, and Brazing, Arc Welding and Cutting; Special Industries, Sawmills; Proposed Rule and Direct Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–023A]

RIN 1218–AC08

Updating OSHA Standards Based on National Consensus Standards; General, Incorporation by Reference; Hazardous Materials, Flammable and Combustible Liquids; General Environmental Controls, Temporary Labor Camps; Hand and Portable Powered Tools and Other Hand Held Equipment, Guarding of Portable Powered Tools; Welding, Cutting, and Brazing, Arc Welding and Cutting; Special Industries, Sawmills

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: OSHA is issuing this notice of proposed rulemaking to delete three references to national consensus standards and two references to industry standards that are outdated. Deleting these references will not reduce employee protections. By eliminating the outdated references, however, OSHA will clarify employer obligations under the applicable OSHA standards and reduce administrative burdens on employers and OSHA. These revisions are part of an overall effort—also explained in today's **Federal Register**—to update OSHA standards that reference, or that include language taken directly from, outdated consensus standards.

DATES: Comments and requests for an informal public hearing must be submitted by the following dates:

- Hard copy: Your comments or hearing requests must be submitted (postmarked or sent) by December 27, 2004.
- Electronic transmission and facsimile: Your comments or hearing requests must be sent by December 27, 2004.

ADDRESSES: You may submit written comments or hearing requests to this proposed rule—identified by docket number S–023A or RIN number 1218–AC08—by any of the following methods:

- Federal eRulemaking Portal: *http://www. regulations. gov.* Follow the instructions for submitting comments.
- OSHA Web site: *http://ecomments.osha.gov.* Follow the instructions for submitting comments on OSHA's web page.
- Fax: If your written comments are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648.
- Regular mail, express delivery, hand delivery and courier service: Submit three copies to the OSHA Docket Office, Docket No. S–023A, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–2625, Washington, DC 20210; telephone (202) 693–2350. (OSHA's TTY number is (877) 889–5627). OSHA Docket Office hours of operation are 8:15 a.m. to 4:45 p.m., EST.

Instructions: All comments received will be posted without change to *http://dockets.osha.gov*, including any personal information provided. OSHA cautions you about submitting personal information such as social security numbers and birth dates.

OSHA requests comments on all issues related to this action. OSHA also welcomes comments on the Agency's findings that there are not negative economic or other regulatory impacts of this action on the regulated community. If OSHA receives no significant adverse comment on the direct final rule, OSHA will publish a **Federal Register** document confirming its effective date and withdrawing this proposal. Such confirmation may include minor stylistic or technical changes to the revisions. For the purpose of judicial review, OSHA views the date of confirmation of the effective date of the direct final rule as the date of issuance. If OSHA receives significant adverse comment on the direct final rule, it will withdraw that rule and proceed with this proposed rule.

Docket: For access to the docket to read background documents or comments received, go to *http://dockets.osha.gov.* Contact the OSHA Docket Office for information about materials not available through the OSHA webpage and for assistance in using the webpage to locate docket submissions.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries contact George Shaw, Acting Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999. For technical inquiries, contact Ted Twardowski, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2070 or fax (202) 693–1663. Copies of this **Federal Register** notice are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, DC 20210; telephone: (202) 693–1888. Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's webpage at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

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I. Direct Final Rulemaking

This notice of proposed rulemaking is being published on the same day as a companion direct final rule, which is essentially identical to this proposal. In direct final rulemaking, an agency publishes a final rule in the **Federal Register** with a statement that, unless a significant adverse comment is received within a specified period of time, the rule will go into effect. An identical proposed rule is often published at the same time. If any significant adverse comments are received, the agency withdraws the direct final rule and treats the comments as responses to the proposed rule. Direct final rulemaking is used where an agency anticipates that a rule will be non-controversial. Examples include minor substantive changes to regulations and direct incorporations of mandates from new legislation.

For purposes of this direct final rulemaking, a significant adverse comment is one that explains why the revocations would be inappropriate, including challenges to OSHA's underlying premise or approach. In determining whether a comment necessitates withdrawal of the direct final rule, OSHA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. A comment recommending additional changes will not be considered a significant adverse comment unless the comment states why the direct final rule would be ineffective without the addition. If timely significant adverse comments are received, the Agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing the direct final rule no later than February 22, 2005.

In the event the direct final rule is withdrawn because of significant adverse comment, OSHA intends to proceed with the rulemaking by

addressing the comment and publishing a new final rule. If a significant adverse comment is received regarding certain revocations included in the direct final rule, but not others, OSHA may (1) finalize those revocations that did not receive significant adverse comment, and (2) conduct further rulemaking under the proposed rule for the proposed revocations that did receive significant adverse comment. The comment period for the proposed rule runs concurrently with that of the direct final rule. Any significant adverse comment received under the companion direct final rule will be treated as comments regarding the proposed rule.

OSHA has determined that the subject of this rulemaking is suitable for direct final rulemaking. First, OSHA's changes do not compromise the safety of employees. As described below, OSHA's changes will eliminate confusion and clarify employer obligations; as such, they will enhance employee safety. Second, OSHA's changes will result in no additional costs to employers, and may even produce cost savings. Third, OSHA's changes are non-controversial. By revoking the references to the outdated consensus/industry standards, OSHA is updating its requirements in a manner that is consistent with current safety practices and does not reduce the safety of employees.

II. Discussion of Revocations

As explained elsewhere in today's **Federal Register**, OSHA is undertaking a series of regulatory projects to update its standards to reflect the current versions of consensus standards. These regulatory projects will include updating or revoking consensus standards incorporated by reference, and updating regulatory text of current OSHA rules that were adopted directly from the language of outdated consensus standards. This direct final rulemaking is just the first step in OSHA's long-term effort to update or revoke references to outdated consensus standards.

In this document OSHA is proposing to revoke references to three national consensus standards and two industry standards.[1] All of the references are to standards issued over 35 years ago, and in one case over 60 years ago. Some are no longer available to the public through the issuing Standards Development Organization (SDO). Three of the references have been withdrawn by their issuing SDOs and not replaced. The reasons for OSHA's decision to revoke each of these references are set forth below.

The Agency has determined that revoking these references will not reduce employee protection. OSHA has made sure that employee protections are maintained with respect to each OSHA standard affected.

1. 29 CFR 1910.106(b)(1)(iii)(a)(2)

OSHA's standard for Flammable and Combustible Liquids, 29 CFR 1910.106, incorporates by reference an industry standard that has been withdrawn by the issuing SDO and is no longer available to the public through the issuing SDO. Existing 1910.106(b)(1)(iii)(a) reads in pertinent part as follows:

> (iii) *Atmospheric tanks.* (a) Atmospheric tanks shall be built in accordance with acceptable good standards of design. Atmospheric tanks may be built in accordance with the following consensus standards that are incorporated by reference as specified in § 1910.6:
>
> * * * * *
>
> (2) American Petroleum Institute Standards No. 12A, Specification for Oil Storage Tanks with Riveted Shells, Seventh Edition, September 1951, or No. 650, Welded Steel Tanks for Oil Storage, Third Edition, 1966.

OSHA is proposing to delete the reference to American Petroleum Institute Standard No. 12A, Specification for Oil Storage Tanks with Riveted Shells, Seventh Edition, September 1951 (API 12A) in 1910.106(b)(1)(iii)(a)(2).

API 12A includes design specifications for tanks with riveted shells used for oil storage. OSHA incorporated API 12A into 29 CFR 1910.106 because it was referenced in NFPA 30–1969, which served as one of the sources for the standard. API 12A was withdrawn in 1974. The issuing SDO has not replaced it and has not incorporated its provisions into another consensus standard. Further, API 12A is no longer publicly available through the American Petroleum Institute.

API 12A was included in 1910.106(b)(1)(iii)(a) to provide employers with one means of complying with the general requirement for atmospheric tanks to be ''built in accordance with acceptable good standards of design.'' The use of API 12A was not required by the standard. OSHA's revocation of the 1951 standard does not change an employer's responsibility for constructing properly designed atmospheric tanks under 1910.106(b)(1)(iii)(a).

The other standards referenced in § 1910.106 have been updated by their respective organizations in recent years. OSHA intends to review these standards and update its references to them, as appropriate, in the future. In this limited rulemaking, however, OSHA is proposing to revise 1910.106(b)(1)(iii)(a)(2) to read as follows:

> American Petroleum Institute Standard No. 650, Welded Steel Tanks for Oil Storage, Third Edition, 1966.

2. 29 CFR 1910.142(c)(4)

The OSHA standard for Temporary Labor Camps, 29 CFR 1910.142, incorporates by reference a national consensus standard that was issued 60 years ago. This referenced standard was withdrawn by the issuing SDO in 1972 and has not been replaced. Existing 1910.142(c)(4) reads:

> Where water under pressure is available, one or more drinking fountains shall be provided for each 100 occupants or fraction thereof. The construction of drinking fountains shall comply with ANSI Standard Specifications for Drinking Fountains, Z4.2–1942, which is incorporated by reference as specified in § 1910.6. Common drinking cups are prohibited.

OSHA is proposing to delete from this provision the requirement that drinking fountains comply with ANSI Z4.2–1942.

ANSI Z4.2–1942 was issued in 1942. It provides guidance concerning the construction of drinking fountains based on the technology and construction practices that existed in 1942. ANSI Z4.2–1942 contains ten specific recommendations regarding the construction of drinking fountains. All of these recommendations use advisory ''should'' language. Because the provisions are advisory only, they are unenforceable. *See* 49 FR 5318, February 10, 1984; *cf. Marshall* v. *Pittsburgh-Des Moines Steel Company*, 584 F.2d 638, 643–44 (3d. Cir. 1978).

OSHA has concluded that the reference to ANSI Z4.2–1942 should be removed for two primary reasons. First, as stated above, because the specific recommendations in ANSI Z4.2–1942 use advisory language, they are unenforceable.

Second, referencing recommendations issued over 60 years ago for the construction of drinking fountains does not enhance the safety and health of employees. The technology for constructing drinking fountains has changed significantly since the 1940's. Since 1942, a number of drinking

[1] The two industry standards OSHA is proposing to revoke—American Petroleum Institute Standards No. 12A, Specification for Oil Storage Tanks with Riveted Shells, Seventh Edition, September 1951 and Recommended Safe Practices for Gas-Shielded Arc Welding, A6.1–1966, American Welding Society—are incorporated by reference in OSHA standards on Flammable and Combustible Liquids and Welding, Cutting, and Brazing, respectively. These two industry standards were adopted by the Agency because they were cited in two national consensus standards (NFPA 30–1969 and ANSI Z–49.1–1967) that served as sources for the OSHA standards.

fountain units have become available to employers that, while not strictly manufactured in accordance with ANSI Z4.2–1942, are constructed pursuant to good engineering practices and are safe to use at temporary labor camps. It does not serve employers or employees to reference construction specifications that do not consider this new technology.

For these reasons, OSHA is proposing to revise paragraph 1910.142(c)(4) to read:

> Where water under pressure is available, one or more drinking fountains shall be provided for each 100 occupants or fraction thereof. Common drinking cups are prohibited.

3. 29 CFR 1910.243(e)(1)(i)

Paragraph (e)(1)(i) of the OSHA standard for the Guarding of Portable Power Tools, 29 CFR 1910.243, incorporates a 1968 national consensus standard for power lawnmowers:

> Power lawnmowers of the walk-behind, riding-rotary, and reel power lawnmowers designed for sale to the general public shall meet the design specifications in ''American National Standard Safety Specifications for Power Lawnmowers'' ANSI B71.1-X1968, which is incorporated by reference as specified in § 1910.6. These specifications do not apply to a walk-behind mower which has been converted to a riding mower by the addition of a sulky. Also, these specifications do not apply to flail mowers, sicklebar mowers, or mowers designed for commercial use.

OSHA is proposing to revoke the reference to American National Standard Safety Specifications for Power Lawnmowers ANSI B71.1-X1968 (ANSI B71.1–1968) in this provision and replace it with a reference to the general machine guarding requirements contained in 29 CFR 1910.212. OSHA is also proposing to remove the sentences that describe the types of mowers for which the specifications in ANSI B71.1–1968 do not apply.

ANSI B71.1–1968 provides safety specifications for walk-behind and riding rotary motors, and walk-behind and rotary reel mowers ''designed for sale to the general public.'' ANSI B71.1–1968 states that it is not intended to cover sulky-type mowers, flail mowers, sicklebar mowers, or mowers designed for commercial use. ANSI B71.1–1968, p. 7.

ANSI has updated and expanded the scope of B71.1 significantly several times since 1968. Whereas the 1968 version was approximately 10 pages long, the 1998 edition is approximately 60 pages long. The 1998 edition contains specifications for a number of different walk-behind and ride-on mowers, including: (1) Reel and rotary walk-behind power lawn mowers, (2) reel and rotary ride-on power lawn mowers, (3) ride-on power lawn tractors with mower attachments, (4) ride-on power lawn and garden tractors with mower attachments, and (5) lever steer ride-on mowers. In addition, while the 1968 version was not intended to apply to sulky-type, flail, and sicklebar mowers, as well as mowers designed for commercial use, the 1998 version is ''intended to apply to products specifically intended as consumer products for the personal use of a consumer around a house.'' Its requirements ''are not intended to apply to commercial products customarily used by hired operators. * * *'' ANSI B71.1–1998, p. 1.

When OSHA promulgated 1910.243(e), it incorporated many of the specifications contained in ANSI B71.1–1968 directly into the regulatory text. In fact, the vast majority of the requirements for walk-behind and riding rotary mowers found in ANSI B71.1–1968 are included in 1910.243(e). The only requirements not included directly in 1910.243(e) are those dealing with the testing of certain mowers and a handful of provisions concerning reel mowers. OSHA also incorporated the scope section of ANSI B71.1–1968 into paragraph 1910.243(e)(1)(i). Paragraph 1910.243(e)(1)(i) thus requires power lawnmowers designed for sale ''to the general public'' to follow ANSI B71.1–1968, but not power lawnmowers designed ''for commercial use''; power lawnmowers designed for commercial use must follow the guarding requirements of 29 CFR 1910.212(a)(1) and (a)(3)(ii). *See* Memorandum from John Miles to Regional Administrators, ''Misapplication of Power Lawnmower Standard 29 CFR 1910.243(e),'' 1986 (Ex. 2–1).

In order to simplify and clarify the scope and coverage of § 1910.243, OSHA is proposing to delete the reference to ANSI B71.1–1968 and the final two sentences of paragraph 1910.243(e)(1). The reference to ANSI B71.1–1968 in paragraph 1910.243(e)(1) is particularly confusing, given the limitations of the scope of the consensus standard. It is difficult for employers to determine which lawnmowers are designed for sale to ''the general public'' (covered by ANSI B71.1–1968) and which are designed ''for commercial use'' (not covered by ANSI B71.1–1968). This distinction is also not particularly relevant to protecting employees from the hazards associated with operating power lawnmowers.

OSHA is proposing to replace the reference to ANSI B71.1–1968 with a requirement for employers to ensure that all power lawnmowers meet the minimum guarding requirements of 29 CFR 1910.212. This change does not significantly alter the existing requirements for power lawnmowers ''designed for commercial use,'' which, as stated above, are already required to comply with paragraphs 1910.212(a)(1) and (a)(3)(ii). In addition, it does not markedly alter any existing requirements for power lawnmowers ''designed for sale to the general public.'' Employers must still ensure that power lawnmowers comply with the requirements contained in 1910.243(e), which as stated above, includes the vast majority of the provisions from ANSI B71.1–1968. Ensuring that power lawnmowers are in compliance with 1910.243(e) and the guarding provisions of 29 CFR 1910.212, will adequately protect employees from the hazards associated with operating this machinery. In addition, we are aware that under Consumer Products Safety Commission standards issued in 1979, manufacturers of certain power lawnmowers that are ''consumer products'' must meet specific design requirements for such lawnmowers, including guarding requirements. These standards provide an additional set of protections for employees who use such products on the job.

Finally, OSHA considered updating the 1968 ANSI reference to the 1998 version of ANSI B71.1, but determined that doing so would not clarify the standard. As stated above, the 1998 version applies ''to products specifically intended as consumer products for the personal use of a consumer around a house,'' and not to products ''customarily used by hired operators.'' For OSHA purposes, this scope would raise additional issues for compliance that are not encountered under the existing OSHA standard. OSHA believes that deleting the reference and replacing it with a reference to 29 CFR 1910.212 will both retain the existing degree of employee protection, and remove a continuing source of confusion as to the scope of the referenced standard.

Accordingly, OSHA is proposing to revise 1910.243(e)(1)(i) to read as follows:

> Power lawnmowers of the walk-behind, riding rotary, and reel power lawnmowers shall be guarded in accordance with the machine guarding requirements in 29 CFR 1910.212, General requirements for all machines.

4. 29 CFR 1910.254(d)(1)

The existing OSHA standard for Arc Welding and Cutting, 29 CFR 1910.254, incorporates by reference a 38-year old

industry standard that has been merged with a more recent national consensus standard. Existing 1910.254(d)(1) reads as follows:

> General. Workmen assigned to operate or maintain arc welding equipment shall be acquainted with the requirements of this section and with 1910.252 (a), (b), and (c) of this part; if doing gas-shielded arc welding, also Recommended Safe Practices for Gas-Shielded Arc Welding, A6.1–1966, American Welding Society, which is incorporated by reference as specified in § 1910.6.

For reasons discussed below, OSHA is proposing to delete the reference to Recommended Safe Practices for Gas-Shielded Arc Welding, A6.1–1966, American Welding Society (AWS A6.1–1966).

AWS A6.1–1966 discusses the potential hazards associated with gas-shielded arc welding and gives recommendations (non-mandatory) on personal protective equipment (PPE) and engineering controls to protect employees against such hazards. Compliance with AWS A6.1–1966 was required by ANSI Z49.1–1967, which OSHA used as a source for its welding standards in 29 CFR 1910.254. In 1973, AWS A6.1–1966 was formally merged into ANSI Z49.1 by the consensus standard developers.

OSHA is proposing to revoke the reference to AWS A6.1–1966 because that industry standard is outdated and because virtually all of its coverage is provided elsewhere in OSHA's welding standards. For example, many of the safety-related practices discussed in AWS A6.1–1966 are specifically addressed in 1910.252(a), (b), and (c). While AWS A6.1–1966 gives recommendations for eye protection and protective clothing for employees performing gas-shielded arc welding, 1910.252(b) mandates the specific types of personal protective equipment (PPE) that welders must use. Similarly, AWS A6.1–1966 includes a general recommendation that metal fumes ''can'' be controlled by general ventilation and local exhaust ventilation. Section 1910.252(c), by contrast, provides detailed requirements on ventilation and other means of protecting welders from inhalation hazards. Further, while AWS A6.1–1966 discusses briefly the danger associated with trichloroethylene and perchloroethylene decomposition, 1910.252(c) also discusses the need to keep trichloroethylene and perchloroethylene out of atmospheres ''penetrated by the ultraviolet radiation of gas-shielded welding operations.'' 29 CFR 1910.252(c)(11)(ii).

Paragraph 1910.254(d)(1) requires employees performing arc welding to be ''acquainted with'' 1910.252(a), (b), and (c). These three paragraphs cover virtually all of the recommendations that are found in AWS A6.1–1966 and actually go beyond most of them. In light of this, OSHA does not believe it is necessary to continue to reference the AWS standard in § 1910.254(d)(1).

OSHA also notes that employees performing gas-shielded arc welding are protected from many of the underlying hazards discussed in AWS A6.1–1966 through other applicable OSHA standards. For example, exposures to virtually all of the toxic or hazardous substances that are discussed in AWS A6.1–1966 are regulated by Subpart Z (Toxic and Hazardous Substances) of Part 1910.

Finally, the hazard information included in AWS A6.1–1966 is outdated, particularly compared to the information that employers are already required to provide to employees under OSHA's hazard communication standard, 29 CFR 1910.1200.

For these reasons, OSHA is proposing to revise paragraph 1910.254(d)(1) to read:

> General. Workmen assigned to operate or maintain arc welding equipment shall be acquainted with the requirements of this section and with 1910.252 (a), (b), and (c) of this part.

5. 29 CFR 1910.265(c)(31)(i)

The existing OSHA standard for Sawmills, 29 CFR 1910.265, incorporated by reference a consensus standard that is over 35 years old, has been withdrawn by the issuing SDO, and is included in an unenforceable provision. Existing 1910.265(c)(31)(i) reads:

> Hazardous crossings. Railroad tracks and other hazardous crossings shall be plainly posted and appropriate traffic control devices (American National Standard D8.1–1967 for Railroad-Highway Grade Crossing Protection, which is incorporated by reference as specified in § 1910.6) should be utilized.

OSHA is proposing to delete the provision that employers ''should'' use ''appropriate traffic control devices,'' as set forth in ANSI D8.1–1967.

ANSI D8.1–1967 provides recommendations for signaling, marking, and controlling access to railroad-highway crossings. It does not address hazards specifically associated with crossings in sawmills or other special industries. Rather, the recommendations ''are in the interest of establishing uniformity in traffic control and safety devices at railroad-highway grade crossings.'' ANSI D8.1–1967, p. 4. ANSI withdrew the standard on January 20, 1981 and did not replace it.

OSHA references ANSI D8.1–1967 in an advisory provision; as stated earlier, advisory provisions in mandatory standards are unenforceable. As OSHA found during an earlier rulemaking to delete ''should'' provisions (47 FR 23477, May 28, 1982; 49 FR 5321, February 10, 1984), removing such provisions clarifies employer obligations and enhances OSHA enforcement capabilities. In addition, in the present situation, referencing a 37-year old consensus standard that was intended to address railroad and highway grade crossings—not crossings specifically in sawmills—adds little value to employers and employees in the sawmill industry. At the same time, because OSHA is retaining the mandatory provision in paragraph 1910.265(c)(3)(i) that employers plainly post railroad tracks and other hazardous crossings, employees will continue to be alerted to potential hazards at these dangerous areas.

OSHA is thus proposing to revise the provision to read:

> Hazardous crossings. Railroad tracks and other hazardous crossings shall be plainly posted.

III. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*, is ''to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To achieve this goal Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 655(b), 654(b). A safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment.'' 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if, among other things, a significant risk of material harm exists in the workplace and the proposed standard would substantially reduce or eliminate that workplace risk.

This proposed rule will not reduce the employee protections put into place by the standards being revised; the intent of this proposed rule is to revoke references to consensus standards that are outdated, no longer represent the state-of-the-art in workplace safety, and are confusing to employers and employees. It is therefore unnecessary to determine significant risk, or the extent to which the proposed rule would

reduce that risk, as would typically be required by *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980).

IV. Preliminary Economic Analysis and Regulatory Flexibility Act Certification

This action is not economically significant within the context of Executive Order 12866, or a ''major rule'' under the Unfunded Mandates Reform Act or Section 801 of the Small Business Regulatory Enforcement Fairness Act. The rulemaking would impose no additional costs on any private or public sector entity, and does not meet any of the criteria for an economically significant or major rule specified by the Executive Order or relevant statutes.

This action simply deletes or revises a number of provisions in OSHA standards that are outdated. Therefore, the Agency concludes that the proposed rule would not impose any additional costs on these employers; consequently, the proposal requires no preliminary economic analysis. Furthermore, because the proposed rule imposes no costs on employers, OSHA certifies that it would not have a significant impact on a substantial number of small entities; accordingly, the Agency need not prepare an initial regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

V. Paperwork Reduction Act

This action does not impose new information collection requirements for purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–30.

VI. Federalism

OSHA has reviewed this proposed rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999), which requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. Executive Order 13132 provides for preemption of State law only if there is a clear congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the OSH Act (29 U.S.C. 651 *et seq.*) expresses Congress' intent to preempt State laws where OSHA has promulgated occupational safety and health standards. Under the OSH Act, a State can avoid preemption on issues covered by Federal standards only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement (State-Plan State). 29 U.S.C. 667. Occupational safety and health standards developed by such State-Plan States must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State-Plan States are free to develop and enforce under State law their own requirements for safety and health standards.

This proposed rule complies with Executive Order 13132. As Congress has expressed a clear intent for OSHA standards to preempt State job safety and health rules in areas addressed by OSHA standards in States without OSHA-approved State Plans, this action limits State policy options in the same manner as all OSHA standards. In State with OSHA-approved State Plans, this action does not significantly limit State policy options.

VII. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 26 States or U.S. Territories with their own OSHA-approved occupational safety and health plans must revise their standards to reflect the new standard or amendment, or show OSHA why there is no need for action, *e.g.*, because an existing State standard covering this area is already ''at least as effective'' as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule, must be applicable to both the private and public (State and local government employees) sectors, and must be completed within six months of the publication date of the final Federal rule. These 26 States and territories are: Alaska, Arizona, California, Connecticut (plan covers only State and local government employees), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New Jersey (plan covers only State and local government employees), New York (plan covers only State and local government employees), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands (plan covers only territorial and local government employees), Washington, and Wyoming.

VIII. Unfunded Mandates Reform Act

This proposed rule, which amends subpart A—General (29 CFR 1910.6), subpart H—Hazardous Materials (29 CFR 1910.106), subpart J—General Environmental Controls (29 CFR 1910.142), subpart P—Hand and Portable Powered Tools and Other Hand-Held Equipment (29 CFR 1910.243), subpart Q—Welding, Cutting and Brazing (29 CFR 1910.254), and subpart R—Special Industries (29 CFR 1910.265), has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA). 2 U.S.C. 1501 *et seq.*

For the purposes of the UMRA, the Agency certifies that this proposed rule does not impose any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector, of more than $100 million in any year.

List of Subjects in Part 1910

Flammable materials, Hazardous substances, Occupational safety and health, Signs and symbols.

IX. Authority and Signature

This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order 5–2002 (67 FR 65008), and 29 CFR Part 1911.

Signed at Washington, DC, this 17th day of November, 2004.

John L. Henshaw,

Assistant Secretary of Labor.

Proposed Amendments to Standards

The Occupational Safety and Health Administration is proposing to amend part 1910 of title 29 of the Code of Federal Regulations as set forth below:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart A—General

1. The authority citation for subpart A of part 1910 is revised to read as follows:

Authority: Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Numbers 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable.

Sections 1910.7 and 1910.8 also issued under 29 CFR part 1911. Section 1910.7(f) also issued under 31 U.S.C. 9701, 29 U.S.C. 9a, 5 U.S.C. 553; Pub. L. 106–113 (113 Stat. 1501A–222); and OMB Circular A–25 (dated July 8, 1993) (58 FR 38142, July 15, 1993).

§ 1910.6 [Amended]

2. Section 1910.6 is amended by removing and reserving paragraphs (e)(31); (e)(35); (e)(48); (f)(1); and (i)(2).

Subpart H—Hazardous Materials

3. The authority citation for subpart H of part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

Sections 1910.103, 1910.106 through 1910.111, and 1910.119, 1910.120, and 1910.122 through 126 also issued under 29 CFR part 1911.

Section 1910.119 also issued under section 304, Clean Air Act Amendments of 1990 (Pub. L. 101–549), reprinted at 29 U.S.C. 655 Note.

Section 1910.120 also issued under section 126, Superfund Amendments and Reauthorization Act of 1986 as amended (29 U.S.C. 655 Note), and 5 U.S.C. 553.

4. Paragraph (b)(1)(iii)(*a*)(*2*) of § 1910.106 is revised to read as follows:

§ 1910.106 Flammable and combustible liquids.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(*a*) * * *

(*2*) American Petroleum Institute Standards No. 650, Welded Steel Tanks for Oil Storage, Third Edition, 1966.

* * * * *

Subpart J—General Environmental Controls

5. The authority citation for subpart J of part 1910 is revised to read as follows:

Authority: Secs. 4, 6, and 8, Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable.

Sections 1910.141, 1910.142, 1910.145, 1910.146, and 1910.147 also issued under 29 CFR part 1911.

6. Paragraph (c)(4) of § 1910.142 is revised to read as follows:

§ 1910.142 Temporary labor camps.

* * * * *

(c) * * *

(4) Where water under pressure is available, one or more drinking fountains shall be provided for each 100 occupants or fraction thereof. Common drinking cups are prohibited.

* * * * *

Subpart P—Hand and Portable Powered Tools and Other Hand Held Equipment

7. The authority citation for Subpart P of Part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), or 5–2002 (67 FR 65008), as applicable; 29 CFR part 1911.

Section 1910.243 also issued under 29 CFR part 1910.

8. Paragraph (e)(1)(i) of § 1910.243 is revised to read as follows:

§ 1910.243 Guarding of portable power tools.

* * * * *

(e) * * *

(1) * * *

(i) Power lawnmowers of the walk-behind, riding-rotary, and reel power lawnmowers shall be guarded in accordance with the machine guarding requirements in 29 CFR 1910.212, General requirements for all machines.

* * * * *

Subpart Q—Welding, Cutting, and Brazing

9. The authority citation for Subpart Q of Part 1910 is revised to read as follows:

Authority: Secs. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

10. Paragraph (d)(1) of § 1910.254 is revised to read as follows:

§ 1910.254 Arc welding and cutting.

* * * * *

(d) * * *

(1) *General.* Workmen assigned to operate or maintain arc welding equipment shall be acquainted with the requirements of this section and with 1910.252(a), (b), and (c) of this part.

* * * * *

Subpart R—Special Industries

11. The authority citation for Subpart R of Part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

12. Paragraph (c)(31)(i) of § 1910.265 is revised to read as follows:

§ 1910.265 Sawmills.

* * * * *

(c) * * *

(31) * * *

(i) *Hazardous crossings.* Railroad tracks and other hazardous crossings shall be plainly posted.

* * * * *

[FR Doc. 04–26046 Filed 11–23–04; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–023A]

RIN 1218–AC08

Updating OSHA Standards Based On National Consensus Standards; General, Incorporation by Reference; Hazardous Materials, Flammable and Combustible Liquids; General Environmental Controls, Temporary Labor Camps; Hand and Portable Powered Tools and Other Hand Held Equipment, Guarding of Portable Powered Tools; Welding, Cutting, and Brazing, Arc Welding and Cutting; Special Industries, Sawmills

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Direct final rule.

SUMMARY: OSHA is issuing this direct final rule to delete from OSHA standards three references to national consensus standards and two references to industry standards that are outdated. Deleting these references will not reduce employee protections. By eliminating the outdated references, however, OSHA will clarify employer obligations under the applicable OSHA standards and reduce administrative burdens on employers and OSHA. These revisions are part of OSHA's overall effort—also explained in today's **Federal Register**—to update OSHA standards that reference, or that include language taken directly from, outdated consensus standards.

DATES: This direct final rule will become effective on February 22, 2005, unless significant adverse comment is received by December 27, 2004. If significant adverse comment is received, OSHA will publish a timely withdrawal of this rule.

Comments to this direct final rule must be submitted by the following dates:

- Hard copy: Your comments must be submitted (postmarked or sent) by December 27, 2004.
- Electronic transmission and facsimile: Your comments must be sent by December 27, 2004.

ADDRESSES: Interested persons are requested to submit written data, views, and arguments concerning this direct final rule. You may submit written comments to this direct final rule—identified by docket number S–023A or RIN number 1218–AC08—by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- OSHA Web site: *http://ecomments.osha.gov*. Follow the instructions for submitting comments on OSHA's web page.
- Fax: If your written comments are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648.
- Regular mail, express delivery, hand delivery and courier service: Submit three copies to the OSHA Docket Office, Docket No. S–023A, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–2625, Washington, DC 20210; telephone (202) 693–2350. (OSHA's TTY number is (877) 889–5627). OSHA Docket Office hours of operation are 8:15 a.m. to 4:45 p.m., EST.

Instructions: All comments received will be posted without change to *http://dockets.osha.gov*, including any personal information provided. OSHA cautions you about submitting personal information such as social security numbers and birth dates.

OSHA requests comments on all issues related to this action. OSHA also welcomes comments on the Agency's findings that there are not negative economic or other regulatory impacts of this action on the regulated community. If OSHA receives no significant adverse comment, OSHA will publish a **Federal Register** document confirming the effective date of this direct final rule and withdrawing the companion proposed rule. Such confirmation may include minor stylistic or technical changes to the document. For the purpose of judicial review, OSHA views the date of confirmation of the effective date of this direct final rule as the date of issuance.

If OSHA receives significant adverse comment on this direct final rule, it will withdraw it and proceed with the proposed rule addressing the same standards published in the Proposed Rules section of today's **Federal Register.**

Docket: For access to the docket to read background documents or comments received, go to *http://dockets.osha.gov*. Contact the OSHA Docket Office for information about materials not available through the OSHA webpage and for assistance in using the webpage to locate docket submissions.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries contact George Shaw, Acting Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999. For technical inquiries, contact Ted Twardowski, Directorate of Standards and Guidance, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2070 or fax (202) 693–1663. Copies of this **Federal Register** notice are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1888. Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's webpage at *http://www.osha.gov*.

SUPPLEMENTARY INFORMATION:

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IX. Authority and Signature

I. Direct Final Rulemaking

In direct final rulemaking, an agency publishes a final rule in the **Federal Register** with a statement that, unless a significant adverse comment is received within a specified period of time, the rule will go into effect. An identical proposed rule is often published at the same time. If any significant adverse comments are received, the agency withdraws the direct final rule and treats the comments as responses to the proposed rule. Direct final rulemaking is used where an agency anticipates that a rule will be non-controversial. Examples include minor substantive changes to regulations and direct incorporations of mandates from new legislation.

For purposes of this direct final rulemaking, a significant adverse comment is one that explains why the revocations would be inappropriate, including challenges to OSHA's underlying premise or approach. In determining whether a comment necessitates withdrawal of the direct final rule, OSHA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice and comment process. A comment recommending additional changes will not be considered a significant adverse comment unless the comment states why the direct final rule would be ineffective without the addition. If timely significant adverse comments are

received, the Agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule no later than February 22, 2005.

OSHA is also publishing a companion proposed rule, which is essentially identical to this direct final rule. In the event the direct final rule is withdrawn because of significant adverse comment, OSHA intends to proceed with the rulemaking by addressing the comment and publishing a new final rule. If a significant adverse comment is received regarding certain revocations included in this direct final rule, but not others, OSHA may (1) finalize those revocations that did not receive significant adverse comment, and (2) conduct further rulemaking under the companion proposed rule for the proposed revocations that did receive significant adverse comment. The comment period for the proposed rule runs concurrently with that of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule; the Agency will consider such comments in developing a subsequent final rule.

OSHA has determined that the subject of this rulemaking is suitable for direct final rulemaking. First, OSHA's changes do not compromise the safety of employees. As described below, OSHA's changes will eliminate confusion and clarify employer obligations; as such, they will enhance employee safety. Second, OSHA's changes will result in no additional costs to employers, and may even produce cost savings. Third, OSHA's changes are non-controversial. By revoking the references to the outdated consensus/industry standards, OSHA is updating its requirements in a manner that is consistent with current safety practices, and does not reduce the safety of employees.

II. Discussion of Revocations

As explained elsewhere in today's **Federal Register,** OSHA is undertaking a series of regulatory projects to update its standards to reflect the current versions of consensus standards. These regulatory projects will include updating or revoking consensus standards incorporated by reference, and updating regulatory text of current OSHA rules that were adopted directly from the language of outdated consensus standards. This direct final rulemaking is just the first step in OSHA's long-term effort to update or revoke references to outdated consensus standards.

In this direct final rule OSHA is revoking references to three national consensus standards and two industry standards.[1] All of the references are to standards issued over 35 years ago, and in one case over 60 years ago. Some are no longer available to the public through the issuing Standards Development Organization (SDO). Three of the references have been withdrawn by their issuing SDOs and not replaced. The reasons for OSHA's decision to revoke each of these references are set forth below.

The Agency has determined that revoking these references will not reduce employee protection. OSHA has made sure that employee protections are maintained with respect to each OSHA standard affected.

1. 29 CFR 1910.106(b)(1)(iii)(a)(2)

OSHA's standard for Flammable and Combustible Liquids, 29 CFR 1910.106, incorporates by reference an industry standard that has been withdrawn by the issuing SDO and is no longer available to the public through the issuing SDO. Existing 1910.106(b)(1)(iii)(a) reads in pertinent part as follows:

> (iii) *Atmospheric tanks.* (a) Atmospheric tanks shall be built in accordance with acceptable good standards of design. Atmospheric tanks may be built in accordance with the following consensus standards that are incorporated by reference as specified in § 1910.6:
>
> * * * * *
>
> (2) American Petroleum Institute Standards No. 12A, Specification for Oil Storage Tanks with Riveted Shells, Seventh Edition, September 1951, or No. 650, Welded Steel Tanks for Oil Storage, Third Edition, 1966.

OSHA is deleting the reference to American Petroleum Institute Standard No. 12A, Specification for Oil Storage Tanks with Riveted Shells, Seventh Edition, September 1951 (API 12A) in 1910.106(b)(1)(iii)(a)(2).

API 12A includes design specifications for tanks with riveted shells used for oil storage. OSHA incorporated API 12A into 29 CFR 1910.106 because it was referenced in NFPA 30–1969, which served as one of the sources for the standard. API 12A was withdrawn in 1974. The issuing SDO has not replaced it and has not incorporated its provisions into another consensus standard. Further, API 12A is no longer publicly available through the American Petroleum Institute.

API 12A was included in 1910.106(b)(1)(iii)(a) to provide employers with one means of complying with the general requirement for atmospheric tanks to be ''built in accordance with acceptable good standards of design.'' The use of API 12A was not required by the standard. OSHA's revocation of the 1951 standard does not change an employer's responsibility for constructing properly designed atmospheric tanks under 1910.106(b)(1)(iii)(a).

The other standards referenced in § 1910.106 have been updated by their respective organizations in recent years. OSHA intends to review these standards and update its references to them, as appropriate, in the future. In this limited rulemaking, however, OSHA is revising 1910.106(b)(1)(iii)(a)(2) to read as follows:

> American Petroleum Institute Standard No. 650, Welded Steel Tanks for Oil Storage, Third Edition, 1966.

2. 29 CFR 1910.142(c)(4)

The OSHA standard for Temporary Labor Camps, 29 CFR 1910.142, incorporates by reference a national consensus standard that was issued 60 years ago. This referenced standard was withdrawn by the issuing SDO in 1972 and has not been replaced. Existing 1910.142(c)(4) reads:

> Where water under pressure is available, one or more drinking fountains shall be provided for each 100 occupants or fraction thereof. The construction of drinking fountains shall comply with ANSI Standard Specifications for Drinking Fountains, Z4.2–1942, which is incorporated by reference as specified in § 1910.6. Common drinking cups are prohibited.

OSHA is deleting from this provision the requirement that drinking fountains comply with ANSI Z4.2–1942.

ANSI Z4.2–1942 was issued in 1942. It provides guidance concerning the construction of drinking fountains based on the technology and construction practices that existed in 1942. ANSI Z4.2–1942 contains ten specific recommendations regarding the construction of drinking fountains. All of these recommendations use advisory ''should'' language. Because the provisions are advisory only, they are unenforceable. *See* 49 FR 5318, February 10, 1984; *cf. Marshall* v.

[1] The two industry standards OSHA is revoking—American Petroleum Institute Standards No. 12A, Specification for Oil Storage Tanks with Riveted Shells, Seventh Edition, September 1951 and Recommended Safe Practices for Gas-Shielded Arc Welding, A6.1–1966, American Welding Society '' are incorporated by reference in OSHA standards on Flammable and Combustible Liquids and Welding, Cutting, and Brazing, respectively. These two industry standards were adopted by the Agency because they were cited in two national consensus standards (NFPA 30–1969 and ANSI Z–49.1–1967) that served as sources for the OSHA standards.

Pittsburgh-Des Moines Steel Company, 584 F.2d 638, 643–44 (3d. Cir. 1978).

OSHA has concluded that the reference to ANSI Z4.2–1942 should be removed for two primary reasons. First, as stated above, because the specific recommendations in ANSI Z4.2–1942 use advisory language, they are unenforceable.

Second, referencing recommendations issued over 60 years ago for the construction of drinking fountains does not enhance the safety and health of employees. The technology for constructing drinking fountains has changed significantly since the 1940's. Since 1942, a number of drinking fountain units have become available to employers that, while not strictly manufactured in accordance with ANSI Z4.2–1942, are constructed pursuant to good engineering practices and are safe to use at temporary labor camps. It does not serve employers or employees to reference construction specifications that do not consider this new technology.

For these reasons, OSHA is revising paragraph 1910.142(c)(4) to read:

> Where water under pressure is available, one or more drinking fountains shall be provided for each 100 occupants or fraction thereof. Common drinking cups are prohibited.

3. 29 CFR 1910.243(e)(1)(i)

Paragraph (e)(1)(i) of the OSHA standard for the Guarding of Portable Power Tools, 29 CFR 1910.243, incorporates a 1968 national consensus standard for power lawnmowers:

> Power lawnmowers of the walk-behind, riding-rotary, and reel power lawnmowers designed for sale to the general public shall meet the design specifications in ''American National Standard Safety Specifications for Power Lawnmowers'' ANSI B71.1–X1968, which is incorporated by reference as specified in § 1910.6. These specifications do not apply to a walk-behind mower which has been converted to a riding mower by the addition of a sulky. Also, these specifications do not apply to flail mowers, sicklebar mowers, or mowers designed for commercial use.

OSHA is revoking the reference to American National Standard Safety Specifications for Power Lawnmowers ANSI B71.1–X1968 (ANSI B71.1–1968) in this provision and replacing it with a reference to the general machine guarding requirements contained in 29 CFR 1910.212. OSHA is also removing the sentences that describe the types of mowers for which the specifications in ANSI B71.1–1968 do not apply.

ANSI B71.1–1968 provides safety specifications for walk-behind and riding rotary motors, and walk-behind and rotary reel mowers ''designed for sale to the general public.'' ANSI B71.1–1968 states that it is not intended to cover sulky-type mowers, flail mowers, sicklebar mowers, or mowers designed for commercial use. ANSI B71.1–1968, p. 7.

ANSI has updated and expanded the scope of B71.1 several times since 1968. Whereas the 1968 version was approximately 10 pages long, the 1998 edition is approximately 60 pages long. The 1998 edition contains specifications for a number of different walk-behind and ride-on mowers, including: (1) Reel and rotary walk-behind power lawn mowers, (2) reel and rotary ride-on power lawn mowers, (3) ride-on power lawn tractors with mower attachments, (4) ride-on power lawn and garden tractors with mower attachments, and (5) lever steer ride-on mowers. In addition, while the 1968 version was not intended to apply to sulky-type, flail, and sicklebar mowers, as well as mowers designed for commercial use, the 1998 version is ''intended to apply to products specifically intended as consumer products for the personal use of a consumer around a house.'' Its requirements ''are not intended to apply to commercial products customarily used by hired operators. * * *'' ANSI B71.1–1998, p. 1.

When OSHA promulgated 1910.243(e), it incorporated many of the specifications contained in ANSI B71.1–1968 directly into the regulatory text. In fact, the vast majority of the requirements for walk-behind and riding rotary mowers found in ANSI B71.1–1968 are included in 1910.243(e). The only requirements not included directly in 1910.243(e) are those dealing with the testing of certain mowers and a handful of provisions concerning reel mowers. OSHA also incorporated the scope section of ANSI B71.1–1968 into paragraph 1910.243(e)(1)(i). Paragraph 1910.243(e)(1)(i) thus requires power lawnmowers designed for sale ''to the general public'' to follow ANSI B71.1–1968, but not power lawnmowers designed ''for commercial use''; power lawnmowers designed for commercial use must follow the guarding requirements of 29 CFR 1910.212(a)(1) and (a)(3)(ii). *See* Memorandum from John Miles to Regional Administrators, ''Misapplication of Power Lawnmower Standard 29 CFR 1910.243(e),'' 1986 (Ex. 2–1).

In order to simplify and clarify the scope and coverage of § 1910.243, OSHA is deleting the reference to ANSI B71.1–1968 and the final two sentences of paragraph 1910.243(e)(1). The reference to ANSI B71.1–1968 in paragraph 1910.243(e)(1) is particularly confusing, given the limitations of the scope of the consensus standard. It is difficult for employers to determine which lawnmowers are designed for sale to ''the general public'' (covered by ANSI B71.1–1968) and which are designed ''for commercial use'' (not covered by ANSI B71.1–1968). This distinction is also not particularly relevant to protecting employees from the hazards associated with operating power lawnmowers.

OSHA is replacing the reference to ANSI B71.1–1968 with a requirement for employers to ensure that all power lawnmowers meet the minimum guarding requirements of 29 CFR 1910.212. This change does not significantly alter the existing requirements for power lawnmowers ''designed for commercial use,'' which, as stated above, are already required to comply with paragraphs 1910.212(a)(1) and (a)(3)(ii). In addition, it does not markedly alter any existing requirements for power lawnmowers ''designed for sale to the general public.'' Employers must still ensure that power lawnmowers comply with the requirements contained in 1910.243(e), which as stated above, includes the vast majority of the provisions from ANSI B71.1–1968. Ensuring that power lawnmowers are in compliance with 1910.243(e) and the guarding provisions of 29 CFR 1910.212, will adequately protect employees from the hazards associated with operating this machinery. In addition, we are aware that under Consumer Products Safety Commission standards issued in 1979, manufacturers of certain power lawnmowers that are ''consumer products'' must meet specific design requirements for such lawnmowers, including guarding requirements. These standards provide an additional set of protections for employees who use such products on the job.

Finally, OSHA considered updating the 1968 ANSI reference to the 1998 version of ANSI B71.1, but determined that doing so would not clarify the standard. As stated above, the 1998 version applies ''to products specifically intended as consumer products for the personal use of a consumer around a house,'' and not to products ''customarily used by hired operators.'' For OSHA purposes, this scope would raise additional issues for compliance that are not encountered under the existing OSHA standard. OSHA believes that deleting the reference and replacing it with a reference to 29 CFR 1910.212 will both retain the existing degree of employee protection, and remove a continuing source of confusion as to the scope of the referenced standard.

Accordingly, OSHA is revising 1910.243(e)(1)(i) to read as follows:

Power lawnmowers of the walk-behind, riding rotary, and reel power lawnmowers shall be guarded in accordance with the machine guarding requirements in 29 CFR 1910.212, General requirements for all machines.

4. 29 CFR 1910.254(d)(1)

The existing OSHA standard for Arc Welding and Cutting, 29 CFR 1910.254, incorporates by reference a 38-year old industry standard that has been merged with a more recent national consensus standard. Existing 1910.254(d)(1) reads as follows:

General. Workmen assigned to operate or maintain arc welding equipment shall be acquainted with the requirements of this section and with 1910.252(a), (b), and (c) of this part; if doing gas-shielded arc welding, also Recommended Safe Practices for Gas-Shielded Arc Welding, A6.1–1966, American Welding Society, which is incorporated by reference as specified in § 1910.6.

For reasons discussed below, OSHA is deleting the reference to Recommended Safe Practices for Gas-Shielded Arc Welding, A6.1–1966, American Welding Society (AWS A6.1–1966).

AWS A6.1–1966 discusses the potential hazards associated with gas-shielded arc welding and gives recommendations (non-mandatory) on personal protective equipment (PPE) and engineering controls to protect employees against such hazards. Compliance with AWS A6.1–1966 was required by ANSI Z49.1–1967, which OSHA used as a source for its welding standards in 29 CFR 1910.254. In 1973, AWS A6.1–1966 was formally merged into ANSI Z49.1 by the consensus standard developers.

OSHA is revoking the reference to AWS A6.1–1966 because that industry standard is outdated and because virtually all of its coverage is provided elsewhere in OSHA's welding standards. For example, many of the safety-related practices discussed in AWS A6.1–1966 are specifically addressed in 1910.252(a), (b), and (c). While AWS A6.1–1966 gives recommendations for eye protection and protective clothing for employees performing gas-shielded arc welding, 1910.252(b) mandates the specific types of personal protective equipment (PPE) that welders must use. Similarly, AWS A6.1–1966 includes a general recommendation that metal fumes ''can'' be controlled by general ventilation and local exhaust ventilation. Section 1910.252(c), by contrast, provides detailed requirements on ventilation and other means of protecting welders from inhalation hazards. Further, while AWS A6.1–1966 discusses briefly the danger associated with trichloroethylene and perchloroethylene decomposition, 1910.252(c) also discusses the need to keep trichloroethylene and perchloroethylene out of atmospheres ''penetrated by the ultraviolet radiation of gas-shielded welding operations.'' 29 CFR 1910.252(c)(11)(ii).

Paragraph 1910.254(d)(1) requires employees performing arc welding to be ''acquainted with'' 1910.252(a), (b), and (c). These three paragraphs cover virtually all of the recommendations that are found in AWS A6.1–1966 and actually go beyond most of them. In light of this, OSHA does not believe it is necessary to continue to reference the AWS standard in § 1910.254(d)(1).

OSHA also notes that employees performing gas-shielded arc welding are protected from many of the underlying hazards discussed in AWS A6.1–1966 through other applicable OSHA standards. For example, exposures to virtually all of the toxic or hazardous substances that are discussed in AWS A6.1–1966 are regulated by Subpart Z (Toxic and Hazardous Substances) of Part 1910.

Finally, the hazard information included in AWS A6.1–1966 is outdated, particularly compared to the information that employers are already required to provide to employees under OSHA's hazard communication standard, 29 CFR 1910.1200.

For these reasons, OSHA is revising paragraph 1910.254(d)(1) to read:

General. Workmen assigned to operate or maintain arc welding equipment shall be acquainted with the requirements of this section and with 1910.252(a), (b), and (c) of this part.

5. 29 CFR 1910.265(c)(31)(i)

The existing OSHA standard for Sawmills, 29 CFR 1910.265, incorporates by reference a consensus standard that is over 35 years old, has been withdrawn by the issuing SDO, and is included in an unenforceable provision. Existing 1910.265(c)(31)(i) reads:

Hazardous crossings. Railroad tracks and other hazardous crossings shall be plainly posted and appropriate traffic control devices (American National Standard D8.1–1967 for Railroad-Highway Grade Crossing Protection, which is incorporated by reference as specified in § 1910.6) should be utilized.

OSHA is deleting the provision that employers ''should'' use ''appropriate traffic control devices,'' as set forth in ANSI D8.1–1967.

ANSI D8.1–1967 provides recommendations for signaling, marking, and controlling access to railroad-highway crossings. It does not address hazards specifically associated with crossings in sawmills or other special industries. Rather, the recommendations ''are in the interest of establishing uniformity in traffic control and safety devices at railroad-highway grade crossings.'' ANSI D8.1–1967, p. 4. ANSI withdrew the standard on January 20, 1981 and did not replace it.

OSHA references ANSI D8.1–1967 in an advisory provision; as stated earlier, advisory provisions in mandatory standards are unenforceable. As OSHA found during an earlier rulemaking to delete ''should'' provisions (47 FR 23477, May 28, 1982; 49 FR 5321, February 10, 1984), removing such provisions clarifies employer obligations and enhances OSHA enforcement capabilities. In addition, in the present situation, referencing a 37-year old consensus standard that was intended to address railroad and highway grade crossings—not crossings specifically in sawmills—adds little value to employers and employees in the sawmill industry. At the same time, because OSHA is retaining the mandatory provision in paragraph 1910.265(c)(3)(i) that employers plainly post railroad tracks and other hazardous crossings, employees will continue to be alerted to potential hazards at these dangerous areas.

OSHA is thus revising the provision to read:

Hazardous crossings. Railroad tracks and other hazardous crossings shall be plainly posted.

III. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*, is ''to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To achieve this goal Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 655(b), 654(b). A safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment.'' 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if, among other things, a significant risk of material harm exists in the workplace and the proposed standard would substantially reduce or eliminate that workplace risk.

This direct final rule will not reduce the employee protections put into place by the standards being revised; the intent of this direct final rule is to revoke references to consensus standards that are outdated, no longer represent the state-of-the-art in workplace safety, and are confusing to employers and employees. It is therefore unnecessary to determine significant risk, or the extent to which the direct final rule would reduce that risk, as would typically be required by *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980).

IV. Final Economic Analysis and Regulatory Flexibility Act Certification

This action is not economically significant within the context of Executive Order 12866, or a ''major rule'' under the Unfunded Mandates Reform Act or Section 801 of the Small Business Regulatory Enforcement Fairness Act. The rulemaking would impose no additional costs on any private or public sector entity, and does not meet any of the criteria for an economically significant or major rule specified by the Executive Order or relevant statutes.

This action simply deletes or revises a number of provisions in OSHA standards that are outdated. Therefore, the Agency concludes that the direct final rule would not impose any additional costs on these employers; consequently, the rule requires no final economic analysis. Furthermore, because the rule imposes no costs on employers, OSHA certifies that it would not have a significant impact on a substantial number of small entities; accordingly, the Agency need not prepare a final regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

V. Paperwork Reduction Act

This action does not impose new information collection requirements for purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–30.

VI. Federalism

OSHA has reviewed this direct final rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999), which requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. Executive Order 13132 provides for preemption of State law only if there is a clear congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the OSH Act (29 U.S.C. 651 *et seq.*) expresses Congress' intent to preempt State laws where OSHA has promulgated occupational safety and health standards. Under the OSH Act, a State can avoid preemption on issues covered by Federal standards only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement (State-Plan State). 29 U.S.C. 667. Occupational safety and health standards developed by such State-Plan States must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State-Plan States are free to develop and enforce under State law their own requirements for safety and health standards.

This direct final rule complies with Executive Order 13132. As Congress has expressed a clear intent for OSHA standards to preempt State job safety and health rules in areas addressed by OSHA standards in States without OSHA-approved State Plans, this rule limits State policy options in the same manner as all OSHA standards. In States with OSHA-approved State Plans, this action does not significantly limit State policy options.

VII. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 26 States or U.S. Territories with their own OSHA-approved occupational safety and health plans must revise their standards to reflect the new standard or amendment, or show OSHA why there is no need for action, *e.g.*, because an existing State standard covering this area is already ''at least as effective'' as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule, must be applicable to both the private and public (State and local government employees) sectors, and must be completed within six months of the publication date of the final Federal rule. These 26 States and territories are: Alaska, Arizona, California, Connecticut (plan covers only State and local government employees), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New Jersey (plan covers only State and local government employees), New York (plan covers only State and local government employees), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands (plan covers only territorial and local government employees), Washington, and Wyoming.

VIII. Unfunded Mandates Reform Act

This direct final rule, which amends subpart A—General (29 CFR 1910.6), subpart H—Hazardous Materials (29 CFR 1910.106), subpart J—General Environmental Controls (29 CFR 1910.142), subpart P—Hand and Portable Powered-Tools and Other Hand-Held Equipment (29 CFR 1910.243), subpart Q—Welding, Cutting and Brazing (29 CFR 1910.254), and subpart R—Special Industries (29 CFR 1910.265), has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq*.

For the purposes of the UMRA, the Agency certifies that this direct final rule does not impose any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector, of more than $100 million in any year.

List of Subjects in Part 1910

Flammable materials, Hazardous substances, Occupational safety and health, Signs and symbols.

IX. Authority and Signature

This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order 5–2002 (67 FR 65008), and 29 CFR part 1911.

Signed at Washington, DC, this 17th day of November, 2004.

John L. Henshaw,

Assistant Secretary of Labor.

Amendments to Standards

■ Part 1910 of title 29 of the Code of Federal Regulations is amended as set forth below:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart A—General

■ 1. The authority citation for subpart A of part 1910 is revised to read as follows:

Authority: Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Numbers 12–71 (36 FR 8754), 8–76 (41 FR

25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable.

Sections 1910.7 and 1910.8 also issued under 29 CFR part 1911. Section 1910.7(f) also issued under 31 U.S.C. 9701, 29 U.S.C. 9a, 5 U.S.C. 553; Pub. L. 106–113 (113 Stat. 1501A–222); and OMB Circular A–25 (dated July 8, 1993) (58 FR 38142, July 15, 1993).

§ 1910.6 [Amended]

■ 2. Section 1910.6 is amended by removing and reserving paragraphs (e)(31); (e)(35); (e)(48); (f)(1); and (i)(2).

Subpart H—Hazardous Materials

■ 3. The authority citation for Subpart H of Part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

Sections 1910.103, 1910.106 through 1910.111, and 1910.119, 1910.120, and 1910.122 through 126 also issued under 29 CFR part 1911.

Section 1910.119 also issued under section 304, Clean Air Act Amendments of 1990 (Pub. L. 101–549), reprinted at 29 U.S.C. 655 Note.

Section 1910.120 also issued under section 126, Superfund Amendments and Reauthorization Act of 1986 as amended (29 U.S.C. 655 Note), and 5 U.S.C. 553.

■ 4. Paragraph (b)(1)(iii)(*a*)(*2*) of § 1910.106 is revised to read as follows:

§ 1910.106 Flammable and combustible liquids.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(*a*) * * *

(*2*) American Petroleum Institute Standards No. 650, Welded Steel Tanks for Oil Storage, Third Edition, 1966.

* * * * *

Subpart J—General Environmental Controls

■ 5. The authority citation for subpart J of part 1910 is revised to read as follows:

Authority: Secs. 4, 6, and 8, Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable.

Sections 1910.141, 1910.142, 1910.145, 1910.146, and 1910.147 also issued under 29 CFR part 1911.

■ 6. Paragraph (c)(4) of § 1910.142 is revised to read as follows:

§ 1910.142 Temporary labor camps.

* * * * *

(c) * * *

(4) Where water under pressure is available, one or more drinking fountains shall be provided for each 100 occupants or fraction thereof. Common drinking cups are prohibited.

* * * * *

Subpart P—Hand and Portable Powered Tools and Other Hand Held Equipment

■ 7. The authority citation for subpart P of part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), or 5–2002 (67 FR 65008), as applicable; 29 CFR part 1911.

Section 1910.243 also issued under 29 CFR part 1910.

■ 8. Paragraph (e)(1)(i) of § 1910.243 is revised to read as follows:

§ 1910.243 Guarding of portable power tools.

* * * * *

(e) * * *

(1) * * *

(i) Power lawnmowers of the walk-behind, riding-rotary, and reel power lawnmowers shall be guarded in accordance with the machine guarding requirements in 29 CFR 1910.212, General requirements for all machines.

* * * * *

Subpart Q—Welding, Cutting, and Brazing

■ 9. The authority citation for subpart Q of part 1910 is revised to read as follows:

Authority: Secs. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

■ 10. Paragraph (d)(1) of § 1910.254 is revised to read as follows:

§ 1910.254 Arc welding and cutting.

* * * * *

(d) * * *

(1) *General.* Workmen assigned to operate or maintain arc welding equipment shall be acquainted with the requirements of this section and with 1910.252 (a), (b), and (c) of this part.

* * * * *

Subpart R—Special Industries

■ 11. The authority citation for subpart R of part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

■ 12. Paragraph (c)(31)(i) of § 1910.265 is revised to read as follows:

§ 1910.265 Sawmills.

* * * * *

(c) * * *

(31) * * *

(i) Hazardous crossings. Railroad tracks and other hazardous crossings shall be plainly posted.

* * * * *

[FR Doc. 04–26045 Filed 11–23–04; 8:45 am]

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Federal Register

Wednesday,
November 24, 2004

Part VIII

Department of Homeland Security

Transportation Security Administration

49 CFR Part 1572

Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Driver's License; Final Rule

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Part 1572

[Docket No. TSA–2003–14610; Amendment No. 1572–4]

RIN 1652–AA17

Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Driver's License

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Interim final rule; request for comments.

SUMMARY: TSA is amending standards relating to security threat assessments of commercial truck drivers who are authorized to transport hazardous materials. TSA is adding definitions, and making organizational and substantive changes to the current standards codified at 49 Code of Federal Regulations (CFR) part 1572. First, this rule requires each State to declare whether it wishes to capture and submit fingerprints, applicant information, and fees itself, or alternatively chooses to have TSA complete those tasks. Second, TSA is changing the standards to permit certain aliens who are qualified to hold a commercial drivers license to apply for a security threat assessment. Third, TSA is removing one felony offense, simple drug possession, from the list of disqualifying crimes, and adding unlawful purchase, receipt, transfer, shipping, transporting, import, export, and storage of a firearm or explosives to the list. TSA is reclassifying the criminal offense of arson as an interim rather than permanent disqualifier, and reclassifying the offense of murder as a permanent rather than an interim disqualifier. TSA now prohibits individuals convicted of the most serious crimes, such as treason, from applying for a waiver. TSA is increasing the response time limits for appeals and waivers. TSA is changing the rule concerning transferring a hazardous materials endorsement from one State to another so that drivers do not have to undergo a new background check when obtaining a license in a new State, subject to some restrictions. TSA is enhancing the appeal procedures for an individual who is determined to pose a security threat as a result of the intelligence-related check. The rule moves the start date of the fingerprint-based checks for transfer and renewal applicants to May 31, 2005. The rule no longer requires the States to forward all driver applications to TSA, but the States must retain the applications for one year. States that elect to collect fingerprints and driver information must submit the information and fingerprints electronically, with some initial assistance from TSA. Finally, TSA is reducing the amount of advance notice the States must provide to drivers who hold hazardous materials endorsements regarding the need for a security threat assessment upon renewal. TSA is making these changes in response to comments received from the affected parties and to clarify further the implementation of this program.

DATES: *Effective Date:* This rule is effective November 24, 2004.

Comment Date: Submit comments by December 27, 2004.

ADDRESSES: You may submit comments, identified by the TSA docket number to this rulemaking, using any one of the following methods:

Comments Filed Electronically: You may submit comments through the docket Web site at *http://dms.dot.gov*. Please be aware that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the applicable Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov*.

You also may submit comments through the Federal eRulemaking portal at *http://www.regulations.gov*.

Comments Submitted by Mail, Fax, or In Person: Address or deliver your written, signed comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001; Fax: 202–493–2251.

Comments on Paperwork Collection: Comments may be faxed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: DHS–TSA Desk Officer, at (202) 395–5806. Comments may be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: DHS–TSA Desk Officer.

Declarations Submitted by the States: Address the State Declarations required in § 1572.13(f) to: Program Manager, Credentialing Program Office, 601 S. 12th St., 8th floor, Arlington, VA, 22202.

Reviewing Comments in the Docket: You may review the public docket containing comments in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is located on the plaza level of the NASSIF Building at the Department of Transportation address above. Also, you may review public dockets on the Internet at *http://dms.dot.gov*.

See **SUPPLEMENTARY INFORMATION** for format and other information about comment submissions.

FOR FURTHER INFORMATION CONTACT: Kevin Johnson, Credentialing Program Office, Transportation Security Administration HQ, East Building, 601 South 12th Street, Arlington, VA 22202–4220; telephone (571) 227–2155; e-mail *Kevin.Johnson@dhs.gov*.

Christine Beyer, Office of Chief Counsel, Transportation Security Administration, HQ, East Tower, 601 South 12th St., Arlington, VA 22202–4220; 571–227–2657; e-mail: *Christine.Beyer@dhs.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

This Interim Final Rule is being adopted without prior notice and prior public comment. However, to the maximum extent possible, TSA provides an opportunity for public comment on regulations issued without prior notice. Accordingly, TSA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the requirements in this document. See **ADDRESSES** above for information on where to submit comments.

With each comment, please include your name and address, identify the docket number at the beginning of your comments, and give the reason for each comment. The most helpful comments reference a specific portion of the rule, explain the reason for any recommended change, and include supporting data. You may submit comments and material electronically, in person, by mail, or fax as provided under **ADDRESSES,** but please submit your comments and material by only one means. If you submit comments by mail or delivery, submit them in two copies, in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing.

If you want TSA to acknowledge receipt of your comments on this rulemaking, include with your comments a self-addressed, stamped postcard on which the docket number

appears. We will stamp the date on the postcard and mail it to you.

Except for comments containing confidential information and Sensitive Security Information (SSI), we will file all comments we receive in the public docket, as well as a report summarizing each substantive public contact with TSA personnel concerning this rulemaking. The docket is available for public inspection before and after the comment closing date.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late to the extent practicable. We may change this rulemaking in light of the comments we receive.

Availability of Rulemaking Document

You can get an electronic copy using the Internet by—

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) web page (*http://dms.dot.gov/search*);

(2) Accessing the Government Printing Office's web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html;* or

(3) Visiting the TSA's Law and Policy web page at *http://www.tsa.dot.gov/public/index.jsp.*

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this rulemaking.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires TSA to comply with small entity requests for information and advice about compliance with statutes and regulations within TSA's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in **FOR FURTHER INFORMATION CONTACT.** Persons can obtain further information regarding SBREFA on the Small Business Administration's web page at *http://www.sba.gov/advo/laws/law_lib.html.*

Abbreviations and Terms Used in This Document

ATSA—Aviation and Transportation Security Act
ATF—Bureau of Alcohol, Tobacco, Firearms, and Explosives
CDC—Centers for Disease Control and Prevention
CDL—Commercial drivers license
CDLIS—Commercial drivers license information system
CHRC—Criminal history records check
CJIS—Criminal Justice Information Services Division
DHS—Department of Homeland Security
DOJ—Department of Justice
DMV—Department of Motor Vehicles
DOT—Department of Transportation
FBI—Federal Bureau of Investigation
FMCSA—Federal Motor Carrier Safety Administration
HSA—Homeland Security Act
HME—Hazardous materials endorsement
HMR—Hazardous materials regulations
MTSA—Maritime Transportation Security Act
RSPA—Research and Special Programs Administration
SEA—Safe Explosives Act
TSA—Transportation Security Administration
USA PATRIOT Act—Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act

I. Background

In response to the September 11 terrorist attacks on the United States, Congress passed the Aviation and Transportation Security Act (ATSA), which established the Transportation Security Administration (TSA).[1] TSA was created as an agency within the Department of Transportation (DOT), operating under the direction of the Under Secretary of Transportation for Security. Effective on March 1, 2003, TSA became an agency of the Department of Homeland Security (DHS), and the head of TSA is now the Assistant Secretary for Homeland Security, Transportation Security Administration (Assistant Secretary).

On May 5, 2003, TSA published an interim final rule (May 5 IFR) that requires a security threat assessment of commercial drivers who are authorized to transport hazardous materials in commerce.[2] The May 5 IFR implemented several statutory mandates discussed below, including fingerprint-based criminal history records checks (CHRC), checks against international databases, and appeal and waiver procedures. The May 5 IFR required CHRC to begin no later than November 3, 2003.

TSA requested and received comments from the States, labor organizations, and representatives of the trucking industry. In addition, TSA held working group sessions with the States to discuss potential fingerprinting systems that would achieve the statutory requirements, but would not adversely impact the States. Based on the comments received and our working sessions with the States, TSA issued a technical amendment in November 2003[3] to extend the date on which submission of fingerprints and applicant information would begin to be required. The reasons for the amendment were that a majority of the States could not implement the program by November and TSA did not have authority to collect fees to cover TSA's implementation costs. The amendment required the States to submit fingerprints and applicant information by April 1, 2004, or request an extension of time and produce a fingerprint collection plan by April 1, 2004. All States were required to have the fingerprint collection program in place as of December 1, 2004.

In response to the November 2003 technical amendment, a majority of the States asked for an additional extension of time because they could not begin collecting applicant information or fingerprints by the extended deadline of April 1, 2004. Therefore, on April 6, 2004, TSA published a final rule removing the April 1 date and establishing January 31, 2005, as the date on which CHRC must begin.[4] The Interim Final Rule we publish today reorganizes, clarifies, and adds operating details to the hazmat program.

In October 2003, legislation was enacted that authorized TSA to collect user fees to cover the cost of each security threat assessment.[5] Pursuant to this legislation, TSA on November 10, 2004 (69 FR 65332), published a notice of proposed rulemaking (NPRM) to establish reasonable fees for the threat assessment process. TSA plans to have the implementation of the hazmat security threat assessment program coincide with our ability to collect fees.

II. USA PATRIOT Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) was enacted on October 25, 2001.[6] Section 1012 of the USA PATRIOT Act amended 49 U.S.C. Chapter 51 by adding a new section 5103a titled ''Limitation on issuance of hazmat licenses.'' Section 5103a(a)(1) provides:

> A State may not issue to any individual a license to operate a motor vehicle transporting in commerce a hazardous material unless the Secretary of Transportation has first determined, upon

[1] Pub. L. 107–71, November 19, 2001, 115 Stat. 597.

[2] 68 FR 23852 (May 5, 2003).

[3] 68 FR 63033 (November 7, 2003).

[4] 69 FR 17696 (April 6, 2004).

[5] Department of Homeland Security Appropriations Act, 2004, Section 520, Pub. L. 108–90, October 1, 2003, 117 Stat. 1137.

[6] Pub. L. 107–56, October 25, 2001, 115 Stat. 272.

receipt of a notification under subsection (c)(1)(B), that the individual does not pose a security risk warranting denial of the license.[7]

Section 5103a(a)(2) subjects license renewals to the same requirements.

Section 5103a(c) requires the Attorney General, upon the request of a State in connection with issuance of an HME, to carry out a background records check of the individual applying for the endorsement and, upon completing the check, to notify the Secretary (as delegated to the Assistant Secretary) of the results. The Secretary then determines whether the individual poses a security risk warranting denial of the endorsement. The security threat assessment must consist of: (1) A check of the relevant criminal history databases; (2) in the case of an alien, a check of the relevant databases to determine the status of the alien under U.S. immigration laws; and (3) as appropriate, a check of the relevant international databases through Interpol-U.S. National Central Bureau or other appropriate means.

III. Safe Explosives Act

Congress enacted the Safe Explosives Act (SEA) on November 25, 2002.[8] Sections 1121–23 of the SEA amended section 842(i) of title 18, United States Code, by adding several categories to the list of persons who may not lawfully ''ship or transport any explosive in or affecting interstate or foreign commerce'' or ''receive or possess any explosive which has been shipped or transported in or affecting interstate or foreign commerce.'' Prior to the amendment, 18 U.S.C. 842(i) prohibited the transportation of explosives by any person under indictment for or convicted of a felony, a fugitive from justice, an unlawful user or addict of any controlled substance, and any person who had been adjudicated as lacking mental capacity[9] or committed to a mental institution. The 2002 amendment added three new categories to the list of prohibited persons: aliens, with certain exceptions;[10] persons dishonorably discharged from the armed forces; and former U.S. citizens who have renounced their citizenship. Individuals who violate 18 U.S.C. 842(i) are subject to criminal prosecution.[11] These incidents are investigated by the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) of the Department of Justice and referred, as appropriate, to the United States Attorneys.

However, 18 U.S.C. 845(a)(1) provides an exception to section 842(i) for ''any aspect of the transportation of explosive materials via railroad, water, highway, or air which are regulated by the United States Department of Transportation and agencies thereof, and which pertain to safety.'' Under this exception, if DOT regulations address the transportation security issues of persons engaged in a particular aspect of the safe transportation of explosive materials, then those persons are not subject to prosecution under 18 U.S.C. 842(i) while they are engaged in the transportation of explosives in commerce. TSA issued the May 5 IFR and amendments in coordination with agencies within DOT, the Federal Motor Carrier Safety Administration (FMCSA) and Research and Special Programs Administration (RSPA), and triggered this exception. Therefore, the SEA does not apply to commercial drivers with HMEs while they are engaged in the transportation of explosives in commerce.

IV. The Current Rule

To comply with the mandates of the USA PATRIOT Act, and to trigger the exception in 18 U.S.C. 845(a)(1) for the transportation of explosives, TSA issued the May 5 IFR, technical amendments, and Final Rule (referred to collectively through the remainder of this document as the Current Rule). Under the Current Rule, TSA determines that an individual poses a security threat if he or she: (1) Is an alien (unless he or she is a lawful permanent resident) or a U.S. citizen who has renounced his or her U.S. citizenship; (2) is wanted or under indictment for certain felonies; (3) has a conviction in military or civilian court for certain felonies; (4) has been adjudicated as lacking mental capacity or involuntarily committed to a mental institution; or (5) is considered to pose a security threat based on a review of pertinent databases.

The Current Rule also establishes conditions and procedures under which an individual who has been determined to pose a security threat can appeal the determination. The Current Rule provides a waiver process for those individuals who otherwise could not obtain a hazardous materials endorsement (HME) due to a disqualifying felony conviction or lack of mental capacity. Any holder of an HME who has committed a disqualifying offense is required to surrender the endorsement as of September 2, 2003. Finally, the Current Rule prohibits an individual from holding, and a State from issuing or renewing an HME for an individual unless the individual meets the TSA security threat assessment standards.

V. Response to Public Comments

TSA received over 100 comments from individual commercial drivers, small trucking companies, national and international carriers, labor organizations, State Departments of Motor Vehicles (DMVs), industry associations, and associations representing State government. The discussion below groups the comments by the primary issues raised by the public.

A. Shortage of Time and Resources

The overwhelming majority of the comments are from the States and concern the need for additional time and resources. The States notified TSA that State funding, human resources, and technology are in short supply. Many of the States needed additional

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[7] The Secretary of Transportation delegated the authority to carry out the provisions of this section to the Under Secretary of Transportation for Security/Assistant Secretary. 68 FR 10988, March 7, 2003.

[8] Pub. L. 107–296, November 25, 2002, 116 Stat. 2280.

[9] Since 1970, the Federal explosives law has identified a category of persons prohibited from possessing explosives as ''adjudicated as a mental defective.'' TSA is replacing this term with ''adjudicated as lacking mental capacity.'' However, these terms have the same meaning for the purposes of the Federal explosives law and the TSA hazmat requirements.

[10] The prohibition in the SEA extends to each person—

(5) Who is an alien, other than an alien who—

(A) Is lawfully admitted for permanent residence (as that term is defined in section 101(a)(20) of the Immigration and Nationality Act); or

(B) Is in lawful nonimmigrant status, is a refugee admitted under section 207 of the Immigration and Nationality Act (8 U.S.C. 1157), or is in asylum status under section 208 of the Immigration and Nationality Act (8 U.S.C. 1158), and—

(i) Is a foreign law enforcement officer of a friendly foreign government, as determined by the Secretary in consultation with the Secretary of State, entering the United States on official law enforcement business, and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of this official law enforcement business; or

(ii) Is a person having the power to direct or cause the direction of the management and policies of a corporation, partnership, or association licensed pursuant to section 843(a), and the shipping, transporting, possession, or receipt of explosive materials is in furtherance of such power;

(C) Is a member of a North Atlantic Treaty Organization (NATO) or other friendly foreign military force, as determined by the Attorney General in consultation with the Secretary of Defense, who is present in the United States under military orders for training or other military purpose authorized by the United States and the shipping, transporting, possession, or receipt of explosive materials in furtherance of the authorized military purpose; or

(D) Is lawfully present in the United States with the Director of Intelligence, and the shipment, transportation, receipt, or possession of the explosive materials is in furtherance of such cooperation;* * *''

[11] The penalty for violation of 18 U.S.C. 842(i) is up to ten years imprisonment and a fine of up to $250,000.

State legislative authority to conduct the program and to collect fees to pay for the States' costs in implementing the program. To the fullest extent possible, TSA has issued extensions of time for the start date of the fingerprint-based CHRC to accommodate these requests and to provide TSA time to develop the fee proposed rule, after TSA obtained legislative authority to collect user fees to support the security threat assessment program.

Many of the States raised technical questions concerning the electronic interface that must exist for the States, TSA, and the Federal Bureau of Investigation (FBI) to receive and transmit data. These are daunting issues in light of the fact that each State and the Federal agencies have unique data management systems, with varying levels of sophistication. TSA is building a new Credentialing Screening Gateway System (Screening Gateway) to collect, retain, and transmit all of the information that must be collected from the applicant to conduct a security threat assessment. Once this system is complete, TSA will be prepared to receive all of the data fields required when the applicant provides the required information for an HME. TSA considers the process for collecting applicants' fingerprints for purposes of this regulation—working through State Departments of Motor Vehicles and allowing States either to collect the fingerprints themselves or to ask TSA to do so—as the best process to implement the USA PATRIOT Act's requirements in the near term. DHS is collecting fingerprints for other Departmental programs and expects to implement other programs in the future that will involve fingerprint collection. As all of these programs evolve, DHS will consider whether processes for this program, or for several DHS programs, can be consolidated to improve efficiency while fulfilling security needs. If greater efficiencies are possible, TSA will consider amending this rule, if necessary, to achieve those efficiencies.

TSA is not requiring the States to develop new connectivity with the TSA Screening Gateway. In States that choose to collect fingerprints and applicant information rather than use TSA for that purpose, the State will be responsible for transmitting the information to TSA electronically through the existing Commercial Drivers License Information System (CDLIS), and ensuring that the fingerprints are forwarded to the FBI in a form and manner consistent with FBI and TSA standards. TSA will assist in the electronic transfer of information in States that are in the process of upgrading their systems when the rule becomes effective. In these States, for a short time TSA will accept the information in alternate forms, such as email or facsimiles; and will format or digitize the information into a useable format until the States' computer upgrades are complete. TSA believes that the ability to exchange information electronically will benefit the States, the industry, and TSA in the long run and so TSA encourages the States to opt for this process. If a State knows that it will not be able to transmit the information electronically until after July 2005, however, the State should formally elect to have TSA capture the fingerprints and driver information. TSA can staff the data entry for a short period of time until a State's computer system is upgraded, but TSA does not have the resources to perform that task beyond July 2005.

B. List of Disqualifying Criminal Offenses.

Many individual drivers, trucking companies, and the States submitted comments on the list of disqualifying offenses in the Current Rule. For that reason, TSA reevaluated the list in order to ensure that it is not over- or under-inclusive. As a result, TSA is making several changes to the list of disqualifying crimes.

The list of permanently disqualifying offenses in the Current Rule includes espionage, treason, sedition, a crime involving a transportation security incident, improper transportation of a hazardous material, a terrorist crime, arson, unlawful use of an explosive, and conspiracy to commit any of these crimes. TSA is making four changes to the list of permanently disqualifying offenses: arson is reclassified as an interim rather than a permanent disqualifier, violations of the Racketeer Influenced Corrupt Organizations Act (RICO) are permanently disqualifying if an underlying crime is a permanent disqualifier (such as a terrorist conviction under 18 U.S.C. chapter 113B); TSA is adding unlawful purchase, receipt, transfer, shipping, transporting, import, export or storage of an explosive to former paragraph 1572.103(b)(9); and TSA is reclassifying murder as a permanently disqualifying crime.

TSA is amending the list of interim disqualifying offenses by adding arson and unlawful purchase, receipt, transfer, shipping, transporting, import, export or storage of a firearm, and by reclassifying murder and removing simple drug possession from the list. Possession with intent to distribute remains an interim disqualifying offense.

TSA developed the list of disqualifying felony convictions in consultation with the Department of Justice (DOJ) and DOT, to include those offenses that are reasonably indicative of an individual's predisposition to engage in violent or deceptive behavior that may be predictive of a security threat. Some States suggested that all criminal convictions should be disqualifying. The USA PATRIOT Act requires TSA to ''review relevant criminal databases'' and appropriate international databases to determine whether the applicant poses a security threat. Based on the legislative language and the need to keep commerce moving, TSA believes that disqualification of all drivers with a criminal record is not necessary. Past history and current threat information do not indicate that all persons with a criminal conviction pose a security threat. We believe that the rule lists the criminal offenses that indicate an individual's predisposition to engage in violent or deceptive activity that may reasonably give rise to a security threat.

TSA is removing simple possession of a controlled substance from the list based on comments received and our own analysis. Simple drug possession generally does not involve violence against others or reveal a pattern of deception, as crimes like smuggling or bribery often do. In addition, FMCSA's regulations governing the commercial driver's license program require CDL holders to undergo pre-application, post-accident, and random alcohol and drug testing. 49 CFR part 382. A positive drug or alcohol test will result in restrictions on the driver's CDL or disqualification. TSA believes that these standards act as a strong deterrent against alcohol or drug use while employed as a CDL driver. To the extent that an individual with a simple drug possession conviction presents a threat, the current CDL testing requirements most likely deter dangerous individuals with drug use problems from seeking employment as a hazmat driver. Based on this, and because simple drug possession generally does not fall within the class of crimes involving violence or deception, TSA has determined that there should be no adverse impact resulting from removing conviction for simple possession of a controlled substance from the list of disqualifying offenses. Conviction for possession of drugs with intent to distribute remains a disqualifying crime.

We are reclassifying arson as an interim rather than a permanent disqualifying offense. In reevaluating

the list of most serious crimes—those that disqualify an applicant for life—TSA believes that arson is not always an act of terrorism, as the other permanent disqualifying crimes typically are. Although an arson conviction may be indicative of a very dangerous individual who should not have control of hazardous material shipments, we do not believe that it rises to the same level of threat as espionage and treason do. It remains a disqualifying offense in this IFR, and TSA can carefully consider the underlying facts if a convicted arsonist applies for a waiver to determine whether the facts are indicative of an individual who presents on ongoing, unacceptable risk to security.

We are reclassifying murder as a permanent rather than interim disqualifying offense. Murder is one of the most violent crimes on the list of disqualifiers and indicates a disregard for human life. In reevaluating the standards, TSA has concluded that the crime of murder should be permanently disqualifying.

TSA is adding a RICO offense to the list of permanent disqualifiers if the underlying or predicate racketeering act for the RICO conviction is a permanently disqualifying offense. TSA understands that RICO convictions are often the result of a series or variety of criminal acts that may not be listed in the criminal history records. However, if a defendant is found by the trier of fact, or by his own admission in the course of a guilty plea, to have committed a permanently disqualifying offense as a predicate to a RICO conviction, TSA will consider the RICO conviction as permanently disqualifying. Conversely, where a RICO conviction is based on a series of robberies, the RICO conviction becomes an interim disqualifying offense. TSA does not anticipate that RICO violations will surface often during the security threat assessment process, but wishes to ensure that they are handled consistently and appropriately if they arise.

With respect to a conviction involving improper shipment of a hazardous material under § 1572.103(a)(6), TSA has added the corresponding Federal statutory citation to the rule (49 U.S.C. 5124) to specify the provision of law that is disqualifying. TSA has made this change in response to comments from the Institute of Makers of Explosives (IME) and the National Propane Gas Association (NPGA), in which they expressed concern that a State might charge an individual with a state crime that involves hazardous materials and incorrectly consider it a disqualifying offense under the Current Rule. Section 5124 of title 49, United States Code, provides that a person who knowingly violates section 5104(b) of the law (tampering and marking standards for hazardous materials), or other law in Chapter 51, Transportation of Hazardous Materials, will be fined under title 18 of the Code, or imprisoned, or both. TSA agrees that adding the Federal citation avoids confusion or incorrect application of the law. This amendment clarifies that 49 U.S.C. 5124, or a state law that is comparable, is disqualifying.

TSA has also added the phrase ''or State law that is comparable'' to crimes that include a specific Federal statutory citation to ensure that where a crime is committed pursuant to a State statute equivalent to these Federal statutes, it is clear that a conviction is disqualifying. The language has been added to paragraphs (a)(4), (a)(6), (a)(8), (a)(10) , and (b)(10).

As part of the discussion on disqualifying criminal offenses, it is important to outline the waiver program in the Current Rule and this IFR. TSA's waiver program provides an avenue for drivers with criminal histories to present the circumstances of their crime, evidence of restitution or other sentencing conditions, rehabilitation, and letters of reference. TSA has received approximately 35 waiver requests to date. The rule imposes a lifetime ban on persons convicted of the most serious security-related offenses (such as treason, espionage, and sedition); any driver convicted of one of these felonies is not eligible for a waiver. However, a driver with a conviction for other disqualifying felonies may apply for a waiver of the standard.

C. Immigration Status

With respect to certain aliens, TSA is amending the standards in this rule in response to comments received and TSA's analysis of the industry. The Current Rule permits citizens and lawful permanent residents to apply for a security threat assessment for an HME.

The FMCSA has statutory authority to develop standards for obtaining a CDL. The FMCSA regulations require CDL holders to be domiciled in the licensing State or be issued a nonresident CDL under prescribed procedures.[12] FMCSA's domicile requirement provides that a CDL holder must have a State of Domicile, which is defined as ''the State where a person has his true, fixed, permanent home and principal residence, and where he has the intention of returning whenever he is absent.''[13] FMCSA's regulations also provide for situations in which a CDL operator is domiciled in a foreign jurisdiction that does not test drivers and issue CDLs in accordance with the FMCSA standards, and permits those individuals to obtain a non-resident CDL from a State that does comply with the testing and licensing requirements.[14]

The trucking industry includes many alien drivers, including lawful nonimmigrants, refugees, and asylees. There are areas of the country, particularly the border States, where the concentration of non-citizens is very high. TSA has received correspondence from drivers in the United States under refugee status who understand that they cannot hold an HME under the Current Rule. In addition, their congressional representatives have expressed interest in authorizing these aliens to hold an HME. Employers have also expressed concern that the industry will be adversely impacted if all aliens are prohibited from holding an HME. This concern is particularly acute now because the trucking industry has informed TSA that the current annual employment turnover rate exceeds 80 percent. Employers report that good employees are difficult to find and keep, and often non-citizen employees are highly motivated to begin a trade in the United States once granted lawful status. Background checks are sometimes completed before an alien is granted lawful status or issued evidence of such status, but may not occur in some cases. However, assuming these individuals meet all CDL qualifications and apply for an HME, these applicants would undergo TSA's thorough security threat assessment.

For the reasons listed above, TSA has determined that the security threat assessment standards should be changed to permit nonimmigrant aliens, asylees, and refugees, who are in lawful status and possess valid and unrestricted documentation establishing eligibility for employment to apply for an HME and security threat assessment, if they are qualified to hold a CDL under 49 CFR parts 383 and 384. Any questions concerning the CDL requirements, particularly with respect to domicile, are governed by the FMCSA regulations and State DMV offices. As long as the applicant complies with the FMCSA regulations for obtaining a CDL, is in the country lawfully, is authorized to work in the U.S., successfully completes TSA's security threat assessment, and meets all other

[12] 49 CFR 384.212.

[13] 49 CFR 383.5.

[14] 49 CFR 383.23(b).

applicable standards, the applicant will meet the security threat assessment standards for holding an HME. TSA believes that if these standards are met, a person's status as an alien alone should not disqualify the individual from holding an HME. Aliens in lawful status are permitted to join the U.S. armed services and operate in other modes of transportation, such as flying aircraft in U.S. airspace, as long as they meet all applicable standards. TSA believes hazmat drivers should be treated similarly.

D. Collection of Fingerprints

Commenters asked TSA to permit the submission of fingerprints once and rerun those prints when the driver must renew or transfer an HME. They cite the cost and time needed to collect new fingerprints each time the driver undergoes a new security threat assessment as justification for recycling fingerprints. TSA understands these concerns and continues to develop a process and system to ensure that necessary fingerprint resubmissions are minimized.

E. Preemption

Several commenters asked for clarification or reconsideration of the preemptive effect that this rule has on State or local law. TSA's rule provides minimum standards for a security threat assessment that all 50 States and the District of Columbia must meet. If a State wishes to take additional action to protect its citizens, TSA's rule does not prevent it.

The State is the licensing body for drivers who are State residents and the State has a clear mandate and interest in protecting the residents and drivers within its borders from dangerous drivers. Thus, if a State determines that additional measures should be applied to drivers licensed by the State, and the measures are not inconsistent with TSA's rule, TSA does not wish to preclude the State from establishing them. As long as the State does not nullify or controvert the intent of the standards in this IFR, TSA's rule would not preempt State action. In deference to the State as the licensing body responsible for the welfare of its citizens, TSA believes that complementary State action may be appropriate. For instance, if a State adds a felony or misdemeanor conviction as disqualifying that is not among the list of disqualifying offenses in this rule, TSA's rule does not preempt application of the State law concerning drivers licensed in that State. However, a State is preempted from applying a standard in which the interim disqualifying offenses are no longer treated as disqualifying.

Federal preemption of State driver licensing standards is treated differently from Federal preemption of State laws or regulations governing the transportation of hazardous materials in commerce. The Federal Hazardous Materials Regulations at 49 CFR parts 171–180 are promulgated under the mandate in section 5103(b) of the Federal hazardous materials transportation law [Federal hazardous materials (hazmat) law; 49 U.S.C. 5101 *et seq.*, as amended by section 1711 of the Homeland Security Act of 2002, Public Law 107–296] that the Secretary of Transportation ''prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce.'' One of the primary purposes of Federal hazmat law is to ensure a nationally uniform set of regulations applicable to the transportation of hazardous materials in commerce. Thus, the preemption provisions of Federal hazmat law generally preclude non-Federal governments from imposing requirements applicable to hazardous materials transportation if:

(1) Complying with the non-Federal regulation and complying with Federal hazmat law, the hazmat safety regulations (HMR), a hazardous materials transportation security regulation, or directive issued by the Secretary of Homeland Security is not possible (dual compliance test; 49 U.S.C. 5125(a)(1)); or

(2) The non-Federal requirement is an obstacle to carrying out Federal hazmat law, the HMR, or a hazardous materials transportation security regulation or directive issued by the Secretary of Homeland Security (obstacle test; 49 U.S.C. 5125(a)(2)).

Further, Federal hazmat law preempts a non-Federal requirement applicable to any one of several specified covered subjects if it is not substantively the same as Federal hazmat law, the HMR, or a hazardous materials transportation security regulation or directive issued by the Secretary of Homeland Security (covered subjects test; 49 U.S.C. 5125(b)).

The HMR are not minimum requirements that other jurisdictions may exceed if local conditions warrant; rather, the HMR are national standards and must be uniformly applied across jurisdictional lines. However, another Federal law may authorize non-Federal requirements. 49 U.S.C. 5125(a) and (b). Also, RSPA may waive preemption of a non-Federal requirement if it: (1) Provides the public with at least as much protection as requirements of Federal hazmat law and the HMR, and (2) does not impose an unreasonable burden on commerce. 49 U.S.C. 5125(e).

Most of the questions TSA receives concerning preemption involve the definition of ''conviction'' and whether the State definition or the definition set forth in TSA's rule applies. TSA's definition applies in the context of hazmat drivers, and TSA is amending it in this IFR to clarify the difference between State and Federal expungement standards. The new definition describes what actions constitute an expungement for purposes of the rule and serve to nullify a conviction. By providing the new definition, TSA believes that many of the questions concerning the application of State or Federal ''conviction'' standards are now addressed.

Some commenters have asked whether the TSA rule precludes a State from reviewing State criminal databases, in addition to the CJIS criminal records that TSA will search. Some States have stated that they plan to complete a check of the State records and forward any pertinent information to TSA with the other applicant information for consideration in the security threat assessment. Moreover, some States are required by State law to forward a driver's derogatory criminal history to TSA.

TSA's rule neither requires a State to search nor prevents a State from searching its own criminal records. If a State has the resources to check State criminal history records and forward any pertinent information to TSA during an applicant's security threat assessment, TSA will use the information. The only caveat we must apply is the State record must be transmitted to TSA contemporaneously with the other applicant information that the State submits to TSA. Considering the volume of information that will be exchanged on 2.7 million drivers, TSA and the States must make every effort to keep an applicant's information consolidated. Also, the State must consult with TSA concerning an acceptable format it will use to transmit the State criminal records to make certain TSA staff can easily decipher the record.

F. Privacy Concerns

Several drivers and employers commented on TSA's ability to maintain the confidentiality of a driver's identification information. Some drivers are skeptical that TSA can protect this personal information from use by other government agencies, commercial organizations, or employers. Employers

would like to receive some of the information that will be collected for the security threat assessment. TSA is sensitive to these issues and has established safeguards to ensure that all information will be handled in accordance with the Privacy Act of 1974.[15]

TSA employees and contractors are bound by law and contract to abide by Federal privacy laws to protect personal information from unauthorized disclosure. There are criminal sanctions for individuals who violate these laws. TSA has published its Privacy Act System of Records [16] for this program, detailing the information to be collected, how it will be used, and the routine uses of that information. TSA's System of Records discussed above permits sharing information with employers in its routine uses section. The personal information will be password protected and secured against unauthorized access.

As a matter of efficiency, TSA intends to maintain as much consistency as possible between the current hazmat driver and future maritime programs. The Maritime Transportation Security Act (MTSA)[17] requires a security threat assessment of workers with unescorted access to secure areas of ports, maritime vessels, and facilities. MTSA provides that any information constituting the grounds for denial of a transportation worker identification card must be maintained confidentially by the Secretary; an individual's employer may be informed of whether or not the individual has been cleared.[18] With respect to the hazmat program, any notification TSA makes to an employer will relay whether the driver's endorsement has been revoked so that the employer knows that the driver is not authorized to transport hazmat. Actual criminal history or other dispositive records will not be shared with employers. If TSA determines that an imminent threat exists and additional measures are necessary to secure a facility, TSA may provide additional information to the employer to help prevent a security incident.

It is also important to note that the FBI places restrictions on who may have access to the raw data obtained during a fingerprint-based CHRC. See 28 CFR 50.12. These restrictions would also apply to an employer's use of certain information.

TSA is considering requiring all employers to maintain a list of employees who hold HMEs, so that in the event that TSA wishes to notify an employer that an employee is not authorized to transport hazmat, TSA will have the information necessary to contact the employer. TSA may require each employer to maintain this list on a secure website that TSA can access easily and to update the list periodically. TSA has similar requirements in place in aviation. For instance, each airport must maintain a current list of individuals who have unescorted access to secure areas of an airport, and conduct periodic audits to ensure that the list is accurate. 49 CFR 1542.211. TSA requests comments from the industry concerning methods to establish such a database that would impose the fewest burdens and costs. Also, TSA requests comments on additional measures that would be useful in protecting this information from unauthorized access.

G. Tiered Background Checks

In one comment, an individual driver asked TSA to consider developing a tiered security threat assessment, with more stringent standards in place for the transportation of dangerous goods, such as weapon systems, chemical and biological warfare materials, and bulk fuels. Individuals who haul less dangerous products, such as asbestos, lithium batteries, food coloring, corn syrup, and bleach would undergo a security threat assessment, but with a shorter list of disqualifying offenses. TSA has discussed this principle internally for use across all modes of transportation. Under this approach, individuals with unescorted access to highly sensitive information, equipment, areas, or products would undergo a very intensive background check, and those with access to less sensitive material would complete a check of relevant criminal databases, particularly for outstanding wants and warrants, immigration status, and appropriate terrorist watch lists.

The difficulty with this approach is that it increases the costs, time, and resources necessary to track a particular shipment through the transportation system and make certain that only individuals with the appropriate background check come in contact with the shipment. TSA and DOT faced this problem with explosives shipments. Manufacturers and shippers were not willing to ship explosives in commerce because the SEA was originally going to be implemented in such a way that no felon could transport the explosive. The industry understood that it would not be possible to know at one end of the shipment process who might handle the package before it reaches its destination. In the scenario the commenter proposes, a significant amount of time would have to be spent by the industry to ensure that a box of explosives entering the transportation system in California does not travel through the hands of an individual who had not completed the most stringent security threat assessment before it reaches Vermont.

We note in this regard that the Current Rule, as amended by this IFR, provides for a tiered security threat assessment in that the driver background check requirements apply to drivers who transport ''placarded'' amounts of hazardous materials and select agents. ''Placarded'' amounts and materials are liquid, gaseous, or solid products that DOT has determined to be hazardous in transportation and require special marking and packaging while transported in commerce. (49 CFR part 172). In the May 5 IFR (68 FR 23832) TSA and DOT determined that the most significant security risks associated with the transportation of hazardous materials in commerce involve the transportation of certain radioactive materials, certain explosives, materials that are poisonous by inhalation, certain infectious and toxic substances, and bulk shipments of materials such as flammable and compressed gases, flammable liquids, flammable solids, and corrosives. This list generally correlates to the types and quantities of hazardous materials for which placarding is required. Using the placarding thresholds to trigger enhanced security requirements covers the materials that present the most significant security threats in transportation and provides a relatively straightforward way to distinguish materials that may present a significant security threat from materials that do not. It also provides consistency for the regulated community, thereby minimizing confusion and facilitating compliance.

As the security programs administered by TSA mature, we intend to develop additional refinements to the process while maintaining a high level of security.

H. HME Transfers

Several drivers and State agencies have requested different standards for HME holders who must transfer the HME to a new State of residence. They cite the difficulty a driver faces if he undergoes security threat assessments for example, in February 2005 in Virginia, and must complete a second security threat assessment if he moves

[15] 5 U.S.C. 552a, as amended.

[16] 69 FR 57349 (September 24, 2004).

[17] Pub. L. 107–295, November 25, 2002, 116 Stat. 2064.

[18] 46 U.S.C. 70105(e).

to another State in the following year. Based on calls TSA has received, some drivers transfer State domicile and driver's licenses frequently. These transfers can become very costly for the driver or his employer, and impose additional work on the State DMVs and TSA. Therefore, TSA is amending the rule to permit the States and a transfer HME applicant to complete one security threat assessment for the period of time required in the driver's original State of issuance. For example, a driver in State A, where the renewal period is every four years, who completes a security threat assessment in 2005 and then moves to State B, will not have to complete a second threat assessment until the State A assessment expires in 2009. FMCSA's regulations require renewing the HME at least once every five years, so drivers across the country have nearly identical renewal periods. 49 CFR 383.141(d). Thus, there is no risk that any driver will go more than five years without a security threat assessment.

TSA invites comment from industry and the States on this new standard. TSA anticipates that the States will have to amend internal recordkeeping practices to track the HME transfer applicants, but we believe based on the comments received from the States that this is preferable to initiating a new security threat assessment each time an HME holder transfers to a new State.

I. Applicability of Waivers to § 1572.107 Disqualifications

An organization submitted comments asking TSA to reconsider the disqualifications from eligibility for a waiver under § 1572.107. TSA does not permit applicants who are disqualified under § 1572.107 to apply for a waiver. First, disqualifications under paragraph 1572.107(a) generally are a result of the intelligence-related check and reveal that the applicant may have or has connections to terrorist activity, leading to the determination that the applicant poses a security threat. Once an applicant is determined to pose a security threat due to intelligence-related information, there can be no rational reason to grant him a waiver of the standards. Further, disqualifications under paragraphs 1572.107(a) or (b) are based on individual determinations that, based on all of the circumstances, the applicant poses a threat. This scenario is unlike situations under § 1572.103, in which applicants are disqualified based on a certain criminal history, but where the circumstances surrounding the crime or rehabilitation following conviction might warrant issuing a waiver. Because individual circumstances are taken into account under a determination based on § 1572.107, there is no reason for a waiver.

Applicants disqualified under § 1572.107 may appeal TSA's initial determination that the applicant may pose a security threat on the grounds that TSA's assessment is inaccurate (e.g., due to mistaken identity). If TSA is not persuaded that the appeal should be granted, there is no opportunity for a waiver. TSA is changing this section of the rule to heighten the level of scrutiny that the applicant's appeal will receive. The rule now requires that the Assistant Secretary, rather than the Director, review and make a final determination of appeals that arise under § 1572.107 of the rule.

J. Hazmat Endorsements for Certain Farmers

Some States have asked whether individuals engaged in farming, who are subject to certain exceptions in the FMCSA and RSPA rules, must undergo a security threat assessment. Farmers are not required to obtain a commercial drivers license if they operate their vehicles within a 150-mile radius of the farm. If they transport materials that must be placarded, they must obtain a farm hazmat endorsement, which is attached to a basic operator Class D license. To obtain this endorsement, the driver must pass the regular CDL hazmat written test and a driving test in a representative vehicle.

These drivers are not required to undergo a security threat assessment for an HME because they are not required to obtain a CDL. The requirements in § 1012 of the USA PATRIOT Act are specific to the hazardous materials endorsement on a commercial drivers license. TSA may determine in the future that this population should undergo some form of a security threat assessment under the provisions of the Aviation and Transportation Security Act.[19] However, TSA is not amending this rule to cover this group, because the rule applies to the States and holders of commercial drivers licenses.

K. Acceptance of Background Checks Conducted by Other Agencies

TSA has received inquiries concerning the acceptance of background checks completed by other public and private entities. They urge TSA to recognize these checks as comparable to the security threat assessment required in this rule to avoid duplication of effort and unnecessary cost. Consistent with Homeland Security Presidential Directive-11 on comprehensive terrorist-related screening procedures and Homeland Security Presidential Directive-12 on common identification standards, TSA is committed to ''standardizing'' the security threat assessment process to the fullest extent possible. TSA will continue to work with all appropriate Federal agencies to ensure comparable background checks and threat assessments to avoid duplication of effort and minimize costs. TSA also recognizes that broader Federal Government efforts are underway to develop standardized screening for multiple programs across the Federal Government and the private sector. As these procedures are developed and implemented government-wide, TSA will consult with other Federal agencies to provide reciprocity with respect to comparable security screening programs.

[19] 49 U.S.C. 114.

VI. Summary of This Interim Final Rule

This document published today (referred to throughout the remainder of this document as the IFR) restructures the Current Rule text for clarity and organization. The chart below provides the section number in the Current Rule and the corresponding new section number used in this IFR.

Old section	New section
1572.5(b)	1572.11
1572.5(c)	1572.13(a)–(d)
1572.5(d)(1)	1572.5(c)
1572.5(d)(2)	1572.5(b)
1572.5(e)	1572.9
1572.5(f)	1572.103
1572.5(g)	1572.15(d)(1)
1572.9	1572.201
1572.11	1572.203

This IFR changes the Current Rule by amending the security threat assessment procedures into three distinct phases: the fingerprint-based check, the intelligence-related check, and the final disposition. As the Current Rule requires and under this IFR, TSA adjudicates the results of the fingerprint- and intelligence-related checks. As provided in this IFR and the Current Rule, after adjudication, TSA issues a Determination of No Security Threat to the State if the records do not disclose disqualifying information. TSA issues an Initial Determination of Threat Assessment to the applicant if the results of the threat assessment reveal a disqualifying standard. The applicant may file an appeal of the Initial Determination with TSA, based on assertions that the underlying records are incorrect or the records refer to a different individual. After completion of

an appeal, TSA issues a Final Disposition based on the results of the security threat assessment and appeal. Under the Current Rule and this IFR, TSA administers a waiver program for individuals who do not meet the standards for mental competency or criminal history, but can show rehabilitation to such an extent that they are capable of holding an HME.

In the IFR, TSA is making the following changes to the Current Rule:

- Revise definitions and terms in the rule text to describe the security threat assessment process
- Reorganize the rule text so that it is easier to follow
- Amend the immigration standards to permit lawful nonimmigrants, refugees, and asylees who possess valid evidence of unrestricted employment authorization who are qualified to hold a CDL to apply for a security threat assessment for an HME
- Remove simple possession of a controlled substance from the list of disqualifying offenses
- Reclassify arson as an interim rather than a permanently disqualifying offense
- Add unlawful purchase, receipt, transfer, shipping, transporting, import, export and storage of a firearm or explosive or explosive device to the list of disqualifying offenses
- Reclassify murder as a permanently rather than an interim disqualifying offense
- Make RICO convictions permanently disqualifying if the predicate crimes are permanently disqualifying
- Add the specific statutory citation for the offense of improper transportation of hazmat
- Lengthen the suspense dates in the appeal and waiver processes
- Reduce the amount of advance notice the States must provide HME drivers about the need for a background check upon renewal
- Amend the standards for drivers who are transferring their HME to a new State so that they do not have to undergo a new security threat assessment until the time period established by the State under which the driver's current security threat assessment expires
- Amend the review process for drivers who are disqualified as a result of the intelligence-related check to provide a final determination by the Assistant Secretary rather than the Director
- Remove the requirement that the States must forward each driver application to TSA
- Require the States to retain the application for one year
- Prohibit applicants with certain conviction from applying for a waiver
- Delay the date on which States are required to begin the security threat assessment process for renewals and transfers
- Require electronic submission of the applicant information in States that elect to do the fingerprint collection
- Require the States to notify TSA as to whether the State elects to collect and submit applicant information and fingerprints, or whether the State wants TSA do the collection

Each of these changes is discussed in detail in the preamble of this IFR.

VII. Rulemaking To Establish Fees

Section 1572.13(f) of the IFR provides that each State must decide whether it wants TSA and its agent to collect applicant information, fingerprints, and fees, and inform TSA of the decision no later than December 27, 2004.

The USA PATRIOT Act did not grant TSA authority to collect fees to cover the costs associated with completing security threat assessments on hazmat drivers. However, on October 1, 2003, legislation was enacted requiring TSA to collect reasonable fees to cover the costs of providing credentialing and background investigations in the transportation field, including implementation of the USA PATRIOT Act requirements.[20] Section 520 of the Homeland Security Appropriations Act of 2004 (2004 Appropriations Act) requires TSA to collect fees to pay for the costs of the following: (1) Conducting or obtaining a criminal history records check (CHRC); (2) reviewing available law enforcement databases, commercial databases, and records of other governmental and international agencies; (3) reviewing and adjudicating requests for waivers and appeals of TSA decisions; and (4) any other costs related to performing the background records check or providing the credential.

Section 520 requires that any fee collected must be available only to pay for the costs incurred in providing services in connection with performing the background check or providing the credential. The fee may remain available until expended. TSA must establish this fee in accordance with the criteria in 31 U.S.C. 9701 (General User Fee Statute), which requires fees to be fair and based on (1) costs to the government, (2) the value of the service or thing to the recipient, (3) public policy or interest served, and (4) other relevant facts. To the extent possible, TSA intends for these fees to be relatively consistent for other TSA background check programs.

In this IFR, TSA is requiring States to choose between two fingerprint collection options. Each State must either: (1) Collect and transmit the fingerprints and applicant information of individuals who apply for or renew an HME; or (2) allow an entity approved by TSA (TSA agent) to collect and transmit the fingerprints and applicant information of such individuals. States are required to notify TSA in writing of their choice within 30 days after the date this IFR is published in the **Federal Register**. If a State does not notify TSA in writing of its choice by that date, TSA will assume that the State has chosen the second option and will work with the State to establish a system for a TSA agent to collect fingerprints and applicant information in the State.

The State will be required to operate under the option it chooses until at least January 31, 2008, unless otherwise approved by TSA. TSA is requiring a specific initial time period of three years so that TSA and the TSA agent can adequately assess the overall cost of implementing the program. The fingerprint portion of the threat assessment will be effectively staggered initially as new applicants apply for the first time and as existing HME holders apply to renew their endorsement. If the States could change position on a yearly basis, the TSA agent would make its initial contract bid based on inaccurate cost projections. With a specific time period, the TSA agent can estimate with more certainty how many applicants must be processed, how much equipment is needed, where the collection centers will be located, and the number of employees needed to carry out the collection tasks.

To comply with the mandates of Section 520 of the 2004 Appropriations Act, the USA PATRIOT Act, and the SEA, TSA is issuing a companion notice of proposed rulemaking (Fee NPRM) to establish user fees for individuals who apply to obtain or renew an HME, and thus are required to undergo a security threat assessment in accordance with 49 CFR part 1572. In the Fee NPRM, TSA proposes to establish two new user fees in addition to the FBI fee for performing the CHRC on behalf of government agencies for non-governmental applicants: (1) A fee to cover TSA's costs of performing and adjudicating security threat assessments, appeals, and waivers (Threat Assessment Fee); and (2) a fee to cover the costs of collecting and transmitting fingerprints and applicant information (Information Collection and Transmission Fee).

[20] Department of Homeland Security Appropriations Act, 2004, section 520, Pub. L. 108–90, October 1, 2003, 117 Stat. 1137.

Under the Fee NPRM, if a State opts to collect fingerprints and applicant information itself, the State would be required to (1) collect and remit to TSA the Threat Assessment Fee in accordance with the requirements of the Fee NPRM and (2) collect and remit to the FBI its user fee to perform a criminal history records check. The State then would be free to collect a fee under State law, such as to cover its costs of collecting and transmitting fingerprints and applicant information.

If a State opts to permit a TSA agent to collect and transmit fingerprints and applicant information, the State would not be required to collect and remit to TSA any fees under the Fee NPRM. Rather, a TSA agent would (1) collect and remit to TSA the Threat Assessment Fee and FBI fee; and (2) collect the Information Collection and Transmission Fee (which TSA will use to pay the agent for its services). TSA will remit to the FBI the appropriate FBI fee.

VIII. Section-by-Section Analysis

Section 1572.3 Terms Used in This Part

Section 1572.3 adds and revises definitions of terms used throughout part 1572. The term ''adjudicate'' is added to describe the process by which an individual's security threat assessment is analyzed to determine whether the individual meets the security threat assessment standards. When TSA receives the results of the fingerprint- and intelligence-related checks, TSA analyzes the information for criminal history, immigration status, mental competency, and connections to terrorist activity to determine if the applicant should be disqualified under the standards described in this rule. The process of making this determination is the adjudication process.

''Alien'' means a person not a citizen or national of the United States. This definition is consistent with the definition of that term provided in the USA PATRIOT Act, which defines ''alien'' by referring to the definition provided in section 101(a)(3) of the Immigration and Nationality Act (INA). Section 101(a)(3) of the INA defines ''alien'' as any person not a citizen or national of the United States.

The Current Rule permits lawful permanent residents and U.S. citizens to hold an HME after successfully completing TSA's security threat assessment. This IFR expands the group of potential HME holders to include lawful nonimmigrants, refugees, and asylees who possess valid, unrestricted evidence of employment authorization, so long as they meet the threshold requirement of being qualified to hold a CDL. TSA is making this change in response to comments received from the States, trucking companies, and individual drivers. Many are concerned that prohibiting aliens who are in the United States working lawfully from transporting hazardous materials will adversely impact the movement of commerce in areas where the concentration of non-citizens is high.

TSA has evaluated the potential risks associated with this change and determined that it will not adversely impact security. Almost all of these individuals undergo background and security checks before obtaining lawful immigration status. Then, they will be subject to the full security threat assessment TSA conducts, which includes a variety of international sources, before being authorized to hold an HME. TSA has determined that, based on these facts and the high level of industry interest in permitting certain aliens to transport hazardous materials, the potential security risks have been effectively addressed and these individuals should be permitted to transport hazmat. This decision is discussed in greater detail in TSA's response to comments received.

''Alien registration number'' means the number issued by DHS to an individual when he or she becomes a lawful permanent resident or attains other non-citizen status. We are adding ''or attains other non-citizen status'' to account for the fact that we are now permitting other non-citizens to apply for a hazmat endorsement.

TSA is adding the term ''applicant'' to mean an individual who applies to obtain, renew or transfer an HME. Regardless of which phase the individual is in, the term ''applicant'' can be used to accurately describe the individual for ease of reference.

We are adding a definition for the term ''Assistant Secretary'' in this IFR, because of a slight difference in the IFR concerning which TSA official makes final determinations of appeals and waivers. In this IFR, only the Assistant Secretary, TSA's highest ranking official or his or her appointed designee, can make a final determination on the appeal of a disqualification under § 1572.107. Due to the fact that the information used for these checks may be classified, and therefore not available to the applicant for review, TSA believes that it is appropriate to provide a high level of scrutiny on these final determinations.

The terms ''commercial driver's license'' and ''endorsement,'' are used here as defined in the Current Rule and in FMCSA's regulations at 49 CFR 383.5. We are not making any changes to these definitions.

TSA is changing the definition of ''convicted'' in this rule. In the Current Rule, convicted means any plea of guilty or *nolo contendere*, or any finding of guilt. Under the IFR, TSA will include the effect that a reversal, pardon, or expungement has on a conviction. Each of these actions nullifies the conviction for purposes of determining whether an applicant meets the security threat standards. It is important to note that the definition also explains what an effective expungement is. For purposes of complying with this rule, the expungement must remove the criminal record from the applicant's file and cannot impose any restrictions or disabilities on the applicant. Also, if the applicant is permitted to withdraw a guilty plea or plea of nolo contendere and the case is dismissed, the individual is no longer considered to have a conviction. TSA believes it is necessary to include this level of detail in the definition to ensure that applicants are treated consistently across the country. Procedures on expungements vary from state to state, and may change at any time. Therefore, TSA hopes to avoid inconsistent application of the law against hazmat drivers by providing the new definition.

We are making three changes to the definition of ''date of service'' in § 1572.3. In the Current Rule, date of service is the date of personal delivery; the mailing date shown on a certificate of service; the date shown on the postmark if there is no certificate of service; another mailing date shown by other evidence if there is not certificate of service or postmark; or the date of an e-mail showing when the document was sent. We are changing ''e-mail'' to ''electronic transmission'' to reflect more accurately the type of information exchange that will likely occur among the States, TSA, and TSA's agent. In addition, we are replacing ''the date shown on the postmark if there is no certificate of service'' with ''10 days from the date of mailing, if there is no certificate of service.'' TSA believes that this change is more reasonable, considering the fact that many drivers are away from home for at least a week and may not have enough time to initiate an appeal without this change. Finally, we are changing the language for circumstances where a document is mailed and there is no certificate of service. In these cases, date of service is the date on which the document is mailed to the mailing address designated by the applicant on the application. TSA makes this change to

underscore that TSA considers the information the applicant puts on the application as accurate and will rely on it for service of documents.

The term ''day'' used in the rule means calendar day and is the same definition used in the Current Rule.

''Determination of No Security Threat'' is an administrative determination by TSA that an individual does not pose a security threat that warrants denial of the authorization to transport hazardous materials. Also, TSA will issue a Determination of No Security Threat to the State when TSA issues a waiver. This term is a replacement for ''Notification of No Security Threat'' that is used in the Current Rule, but has the same meaning. TSA will use ''determination'' in place of ''notification'' throughout the definitions.

The term ''Director'' refers to the officer designated by the Assistant Secretary to administer the appeal and waiver programs described in this part, unless the Assistant Secretary is specifically designated in the rule to administer the appeal or waiver program. The Director is authorized to name a designee to perform these duties, except where the IFR specifically designates the Assistant Secretary to administer the appeal or waiver program.

TSA is adding a definition of explosive or explosive device, which includes an explosive or explosive material defined in 18 U.S.C. 232(5), 841(c)–(f), and 844(j), and a destructive device defined in 18 U.S.C. 921(a)(4) and 26 U.S.C. 5845(f). The addition of this definition does not alter the substance of the rule in any way; it simply provides clarity for individuals looking for guidance on the items that constitute an explosive. The list is illustrative, not exhaustive.

''Final Determination of Threat Assessment'' means a final determination by TSA that an individual does not meet the standards required to hold or obtain a hazardous materials endorsement. A Final Determination may not be administratively appealed. In the Current Rule, this action is referred to as a Final Notification of Threat Assessment. We are changing ''notification'' to ''determination'' to reflect more accurately the action being taken.

''Final Disposition'' is a new term in the IFR that describes the actions that must be taken when a security threat assessment is complete.

TSA is adding a definition of ''firearm or other weapon,'' which includes firearms defined in 18 U.S.C. 921(a)(3) or 26 U.S.C. 5845(a) or items contained on the U.S. Munitions Import List at 27 CFR 447.21. The addition of this definition does not alter the substance of the rule in any way; it simply provides clarity for individuals looking for guidance on the items that constitute an explosive. The list is illustrative, not exhaustive.

A ''hazardous material'' means any material that: (1) In accordance with Federal hazardous materials transportation law (49 U.S.C. 5101 *et seq.*), has been determined to pose an unreasonable risk to health, safety, and property when transported in commerce and that is required to be placarded under subpart F of part 172 of the Hazardous Materials Regulations (49 CFR parts 171–180); or (2) any quantity of any material listed as a select agent or toxin by Centers for Disease Control and Prevention (CDC) in 42 CFR part 73. This is the same definition used in section 103 of the Hazardous Materials Transportation Act and in the Current Rule.

DOT evaluates materials to determine whether their respective characteristics, properties, and quantities in transportation merit special marking, storage, and handling procedures. TSA, in consultation with DOT, has determined that non-placarded shipments do not present a sufficient security risk in transportation to warrant application at this time of the TSA background check requirements to persons who possess or transport these materials, including persons subject to 18 U.S.C. 842(i).

''Hazardous materials endorsement (HME)'' is the authorization issued by a State Department of Motor Vehicles (DMV) to transport hazardous materials in commerce. An HME attaches to a truck driver's commercial driver's license (CDL), which is also issued by a State DMV.

''Incarceration'' means confinement to a jail, half-way house, treatment facility, or other institution, on a full or part-time basis pursuant to a sentence imposed due to a conviction. This definition is taken from a statutory definition of ''imprisoned'' in 22 U.S.C. 2714, which relates to denial of passports due to certain drug offense convictions. It is the same as the definition used in the Current Rule. We have used this definition of incarceration because it is used in similar Federal regulatory programs, such as those involving the issuance or approval of passports. See 5 CFR 890.1003; 42 CFR 1001.2.

TSA is adding a definition for ''imprisoned or imprisonment,'' which is a new term used in § 1572.107. It means confined to a prison, jail, or institution for the criminally insane, on a full-time basis pursuant to a sentence imposed as the result of a criminal conviction or finding of not guilty by reason of insanity. Time spent confined or restricted to a half-way house, treatment facility, or similar institution pursuant to a sentence imposed as the result of a criminal conviction or finding of not guilty by reason of insanity does not constitute imprisonment for purposes of this rule. TSA added this term to cover instances in which we believe time spent in a half-way house or treatment facility should not be relevant to determining whether a driver poses a security threat.

''Initial Determination of Threat Assessment'' means an initial administrative determination by TSA that an individual poses a security threat that warrants denial of the authorization to transport hazardous materials. An Initial Determination may be administratively appealed. We are changing this term to ''Initial Determination'' from ''Initial Notification,'' to reflect more accurately the action being taken. In addition, the words ''the authorization for which the individual is applying'' have been deleted to make the language clearer.

''Initial Determination of Threat Assessment and Immediate Revocation'' means an initial administrative determination that an individual poses a security threat that warrants immediate revocation of an HME. Upon issuance of this document, the State must immediately revoke the hazmat endorsement. The driver has an opportunity to appeal this determination, but the appeal transpires after the revocation has occurred. TSA will issue this document only where we believe the driver may pose an imminent threat to transportation, national security, or other individuals. We are adding this definition to distinguish the notification documents used in an immediate revocation from the more common Initial Determination process.

''Lawful permanent resident'' means an individual who has been lawfully admitted for permanent residence in the United States, as defined in 8 U.S.C. 1101. In the statute, ''lawfully admitted for permanent residence'' means ''the status of having been lawfully accorded the privilege of residing permanently in the United States as an immigrant in accordance with the immigration laws, such status not having changed.'' The language in this definition has been changed slightly from the Current Rule,

but substantively, the meaning is the same.

''Mental institution'' means a mental health facility, mental hospital, sanitarium, psychiatric facility, and any other facility that provides diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital. This definition is taken from standards concerning individuals with a mental disability, which ATF promulgated at 27 CFR 478.11. This definition is the same one used in the Current Rule. We are using this ATF definition because we are implementing standards concerning mental capacity and the authorization to transport explosives and other hazmat, which ATF previously administered before TSA published the Current Rule.

The term ''pilot state'' is defined here as a State that chooses to volunteer to begin the complete security threat assessment process prior to January 1, 2005. This definition is used in the Current Rule.

''Revoke'' means the process by which a State cancels, rescinds, withdraws or removes a hazardous materials endorsement. This definition is revised to include all terms a State may have in its statute that are equivalent to the term ''revoke.'' Several States commented that the local statute does not use ''revoke'' and asked that we include other terms consistent with the State statute to ensure that a State does not violate its own statute when it revokes or rescinds a hazardous materials endorsement. TSA's interest is in the cessation of a driver's right to carry hazardous materials, and not to impact the driver's ability to maintain his commercial drivers license.

''State'' means a State of the United States and the District of Columbia. This definition is taken from The Commercial Motor Vehicle Safety Act of 1986, 49 U.S.C. 31301(14), which created the CDL program. This has not changed from the Current Rule.

''Transportation security incident'' means a security incident resulting in a significant loss of life, environmental damage, transportation system disruption, or economic disruption in a particular area. This definition is taken from the Maritime Transportation Security Act (MTSA) (46 U.S.C. 70101). This definition has the same meaning as the definition used in the Current Rule, but is now consistent with the actual legislative language. TSA used ''severe transportation security incident'' in the Current Rule to make clear that the incident must result in significant damage, disruption, or loss of life to be a disqualifying offense in the hazmat program. TSA is making the change to use the actual legislative language to make the IFR consistent with the statute.

''Withdrawal of Initial Determination of Threat Assessment'' is the document TSA issues to an applicant when the security threat assessment process initially indicates that an applicant may pose a security threat, but on appeal, TSA determines that the person does not pose a security threat. For instance, mistaken identity or incomplete court records may have led to an incorrect initial determination.

Section 1572.5 Scope and Standards for Hazardous Materials Endorsement Security Threat Assessment

This section describes the individuals and entities subject to the requirements in Subpart A and the standards those individuals must meet.

Subpart A applies to State agencies that are responsible for issuing commercial drivers licenses and HMEs, and applicants who hold or apply for a new, renewal or transfer HME.

The standards TSA applies to determine whether an individual poses or is suspected of posing a security threat that warrants denial of an HME have been established by statute, the USA PATRIOT Act and the Safe Explosives Act. For the purposes of this IFR, an applicant does not pose a security threat if he or she (1) does not have a disqualifying criminal offense described in § 1572.103; (2) meets the immigration status requirements described in § 1572.105; (3) does not pose a security threat as described in § 1572.107; and (4) has not been adjudicated as lacking mental capacity as described in § 1572.109. This paragraph also explains that the security threat assessment will be based on the individual's fingerprints, name, and other identifying information.

Section 1572.7 Waivers of Hazardous Materials Endorsement Security Threat Assessment Standards

This section describes the individuals who may apply to TSA for a waiver. Applicants who have been convicted of certain criminal offenses and those who have been declared mentally incompetent in the past may apply for a waiver. Individuals convicted of treason, sedition, espionage, a crime involving a transportation security incident, and a crime of terrorism are not eligible for a waiver from TSA. This is a change from the Current Rule, which TSA believes is appropriate given the severity and level of risk these crimes reflect. Individuals who do not meet the immigration standards in § 1572.105 may not apply for a waiver. There is no circumstance or set of facts under which TSA would wish to suspend the application of the lawful immigration categories listed in section 105 to issue a waiver. Additionally, if TSA determines that an individual does not meet the standards in § 1572.107, the applicant is not eligible for a waiver. Granting a waiver to an individual determined to pose a security threat would undermine the purpose of this rule and the statutes that gave rise to it.

Section 1572.9 Applicant Information Required for a Security Threat Assessment for a Hazardous Materials Endorsement

This section describes all of the identifying information an applicant must provide in order for TSA to complete the fingerprint- and intelligence-related checks. The State is required to retain the information for one year, in either paper or electronic form. If the State opts to collect fingerprints and the applicant information, the State must submit applicant information to TSA electronically and the fingerprints to the FBI. If the State chooses to have TSA do the collection, the TSA agent will collect and retain the information, provide a copy of the application to the State, and submit the fingerprints to the FBI. We are requiring essentially the same information as is required in § 1572.5(e) of the Current Rule, but we now add the requirement to provide the applicant's physical identifying information, including hair and eye color, height and weight. Also, we are now requiring the applicant's mailing address, if it differs from the residential address, to facilitate delivering all notifications to the proper location. Finally, we are requesting the name and address of the applicant's current employer(s) so that TSA can notify the employer if a driver poses a security threat and is no longer authorized to transport hazmat.

This section also requires the applicant to acknowledge and certify that he or she meets the standards described in the application and does not have any of the disqualifying offenses. The applicant's certification is given under penalty of law— any false statement or misrepresentation may result in criminal prosecution.

Section 1572.11 Applicant Responsibilities for a Security Threat Assessment for a Hazardous Materials Endorsement

This section describes the standards with which each applicant must comply and the actions the applicant must take

in order to hold an HME. The requirements in this section are found in § 1572.5(b) of the Current Rule. As of September 2, 2003, current HME holders have been required to surrender the endorsement if the individual does not meet the standards described in the Current Rule. Also, applicants have an ongoing responsibility to report any violation of the standards to TSA and surrender the HME within 24 hours of the violation. Paragraph (d) of this section provides that the applicant may submit fingerprints to prove identity or disprove an adverse finding following the intelligence-related check, and must submit fingerprints when applying to obtain or renew an HME. With respect to transferring an HME when a driver changes residences, the driver is not required to undergo a security threat assessment in the new State until the term of years required in the driver's previous State of residence expires.

On October 1, 2003, legislation was enacted requiring TSA to collect reasonable fees to cover the costs of providing credentialing and background investigations in the transportation field, including implementation of the USA PATRIOT Act requirements.[21] As a result, TSA has initiated a proposed rulemaking to determine the reasonable fees that are necessary to cover each phase of TSA's security threat assessment. Paragraph (d)(3) refers to this fee authority and states that the fee TSA may charge in order to cover the cost of the security threat assessment must be paid by the employee or employer. It is important to note that this does not refer to any fees the States may charge to recover their costs, or the fees that the FBI has established to complete the search.

Section 1572.13 State Responsibilities for Issuance of Hazardous Materials Endorsement

This section lists all of the responsibilities that the States must perform in order to ensure that only individuals who meet the security threat assessment standards receive a hazmat endorsement. These requirements are very similar to the requirements in the Current Rule.

Paragraph (a) provides that each State must immediately revoke an individual's hazardous materials endorsement if TSA informs the State that the individual does not meet the standards for security threat assessment in § 1572.5. This provision is intended to address situations in which TSA becomes aware of an individual who may pose an immediate threat and should not be transporting hazardous materials. TSA envisions that this procedure will not occur frequently, but the States must be prepared to revoke an HME quickly if such an individual comes to TSA's attention. Any individual HME holder who falls into this category may appeal this action, as described in § 1572.141(i).

Paragraph (b) provides that as of January 31, 2005, for new HMEs and on May 31, 2005, for renewal and transfer HMEs, no State may issue or renew an HME for a CDL unless the State receives a Determination of No Security Threat from TSA. This IFR provides the later date for HME renewals and transfers in recognition of the States' need for additional time and resources to implement this program. TSA has completed a name-based check on all current HME holders and reruns this list periodically. TSA has disqualified those individuals that pose a security threat. Therefore, TSA has determined that staggering the implementation should not adversely impact security.

In addition, at least 60 days prior to the expiration date of the individual's endorsement, the State must notify each individual holding a hazardous materials endorsement issued by that State that he or she will be subject to the security threat assessment described in this part as part of an application for renewal of the endorsement. The notice must inform the individual that he or she may initiate the security threat assessment required by this part at any time after receiving the notice, but no later than 30 days before the expiration date of the individual's endorsement. If the individual does not initiate the security threat assessment at least 30 days before the expiration, their HME may expire before the security threat assessment is complete.

The timelines described in paragraph (b) have been shortened from the 180/90-day notification deadlines in the Current Rule as a result of comments received from the States and TSA's reconsideration of this requirement. Initially, TSA established the 180/90-day notification requirements in order to provide HME holders sufficient time to seek other employment if they believe they may be disqualified. However, now that the driver self-reporting requirement in § 1572.11 is in effect (as of September 2, 2003) those drivers must surrender their endorsement and may seek a waiver under § 1572.143.

Representatives of the trucking industry have expressed concern that shortening this advance notice time period from 180 days to 60 may not provide drivers enough time to complete the security threat assessment before the HME expires. If a driver begins the assessment 60 days prior to expiration of his HME, but receives an adverse initial finding, appeals it and then applies for a waiver, companies fear that drivers will not be available to transport hazmat because the HMEs will expire prior to completion of the appeal and waiver processes. Nothing in the rule prohibits the State, employer, or driver from beginning the security threat assessment more than 60 days prior to expiration of the HME. If a State, driver, or employer wishes to start the process earlier, they may do so.

In addition, TSA is adding paragraph (b)(3), which provides that the States may not begin processing renewal and transfer applicants prior to March 31, 2005'60 days before the fingerprint start date for renewal and transfer applicants. TSA is adding this requirement to ensure that TSA and State resources will be focused on new applicants as the nationwide implementation begins. TSA believes this requirement may minimize process, paperwork, and computer problems that are more likely to occur when a program of this size first begins.

Paragraph (c) provides that a State may volunteer to begin the security threat assessment program prior to January 31, 2005, if TSA approves the process the State intends to use. These Pilot States may not revoke, issue, renew or transfer a hazardous materials endorsement for a CDL unless the Pilot State: (1) collects the information required in § 1572.9; (2) collects and submits fingerprints in accordance with procedures approved by TSA; and (3) receives a Determination of No Security Threat or Final Determination of Threat Assessment from TSA. This provision appeared in the Current Rule and is intended to address any State that is ready to proceed prior to January 2005.

Paragraph (d) provides that a State may extend the expiration date of the HME for 90 days if TSA has not provided a Final Determination of Threat Assessment or Determination of No Security Threat before the endorsement expires. Any additional extensions must be approved in advance by TSA. This requirement appears in the Current Rule and TSA believes it is necessary to ensure that no applicant loses his or her HME due to unforeseen delays in the TSA or State process. For instance, if TSA or a State knows that a computer problem has developed that will delay a batch of background check data, the rule provides a mechanism for the State to extend the driver's HME. We are adding the 90-day extension limit in the IFR to ensure that an

[21] 2004 Department of Homeland Security Appropriations Act, Section 520, Pub. L. 108–90, October 1, 2003, 117 Stat. 1137.

applicant's HME is not extended indefinitely. TSA believes this time limit should also prevent miscommunication between TSA and the State. For instance, the State may send the appropriate information to TSA and assume TSA is conducting the security threat assessment, but the documents are lost or misidentified and the security threat assessment is not underway. Also, if TSA issues its Determination, but the State does not receive it for some reason, the rule requires communication between TSA and the State to resolve the delay.

Paragraph (e) requires the State to update the driver's permanent record with the results of the security threat assessment and the new expiration date of the HME; notify CDLIS of the results; and revoke or deny the HME within 15 days after receiving TSA's Determination of No Security Threat or Final Determination of Threat Assessment. These actions include updating the applicant's record; notifying CDLIS of the results of the security threat assessment; and revoking or denying the HME based on the results of the check. The rule requires the States to take these actions within 15 days after receipt of the Final Determination of Threat Assessment or the Determination of No Security Threat.

The IFR does not require the State to ''issue'' an HME within 15 days when the applicant successfully completes the security threat assessment, as the Current Rule did. TSA received comments from many States and their Association concerning the extreme hardship this restriction would place on the current licensing systems. In the States' current CDL and HME issuance systems, the renewal periods and expiration dates are tied to the driver's date of birth. All of the States would be required to make major changes to computer systems that contain the CDL and HME data if the expiration date must be tied to the date of issuance rather than date of birth. Technically, the State can deliver the HME to the driver within 15 days after TSA's notification, but its expiration date would run from the driver's birth date, not the date of issuance, as required in the Current Rule. TSA has concluded that the expense and disruption these substantive changes would cause outweigh any advantage gained by having the expiration dates stem from the date of issuance rather than a driver's date of birth. TSA will monitor this process and take additional regulatory action if needed.

New paragraph (f) provides that each State must notify TSA in writing as to whether the State wishes to have TSA collect and submit applicant information and fingerprints, or whether the State plans to undertake this responsibility. TSA must have each State declaration on or before December 27, 2004 and the declaration will remain in place until January 31, 2008, unless otherwise authorized by TSA. Throughout this rulemaking proceeding, approximately half of the States have indicated the desire to collect applicant fingerprints and information, and have the equipment, personnel, and funds to do so. Therefore, TSA is offering this choice to accommodate those State interests. For all other States, TSA, through an agent, will complete these tasks using TSA resources and the user fee collected for this purpose. The States' written declaration must be sent to the Hazmat Program Manager, TSA Credentialing Office, 601 S. 12th St., Arlington, VA 22202.

For TSA to prepare adequately to oversee and administer the fingerprint collection process, and so that any TSA agent can accurately assess costs, TSA must know how many States will complete these collections and how many will opt for TSA to perform these responsibilities. To develop accurate cost estimates necessary to determine the user fee TSA will charge to the applicant or employer, TSA and its agent must assess start-up and operational costs over a period of time. Therefore, the selection each State makes will remain in place until January 31, 2008 unless otherwise authorized by TSA. TSA believes that a shorter time period is not adequate to assess implementation costs on how many collection sites are needed, how much equipment and personnel will be necessary, the time it will take to collect prints in the large versus small States, and other operational issues. Finally, if TSA does not receive a written declaration from a State, TSA and its agent will assume responsibility for the collection and submission process for that State.

It is also important to note that if the State elects to collect applicant fingerprints and information, the State will gather the information that is required by the rule when the driver appears to provide fingerprints and initiate the process. The State must then forward the information to TSA electronically through CDLIS, the fingerprints to the FBI, and the corresponding fees to TSA and the FBI. As stated above, TSA is willing to assist with the electronic transmission of the information for a short period of time to give States enough time to upgrade their computer systems to perform electronic transfers routinely. TSA can devote resources to entering the data manually for a few months as long as the State is in the process of upgrading their system. If the State cannot complete the upgrade by July 2005, then the State should elect to have TSA capture fingerprints and information.

If TSA's agent collects applicant information and fingerprints, TSA will require the TSA agent to collect and remit to TSA the FBI's fee and TSA's threat assessment fee, in a form and manner approved by TSA. Also, the FBI will bill TSA on a monthly basis for the fingerprints submitted by TSA through TSA's agent and processed by the FBI. This process is discussed in the fee NPRM as well.

Depending on how many States elect to have TSA complete the fingerprint collection program and where they are located, drivers licensed in States that opt to have TSA collect fingerprints may be able to submit their fingerprints at any location where TSA has established a collection facility. For instance, if a driver in State A is working outside State A when it is time to submit fingerprints and information and State A elected to have TSA collect fingerprints, the driver may submit fingerprints at a TSA collection site that is much closer to where he is working at the time. In States that opt to do the collection, drivers will most likely have to submit the required information at a State collection point.

As discussed earlier in this document, TSA is conducting a parallel proposed rulemaking to address the amount of the fee that TSA intends to charge for the security threat assessment. TSA encourages all interested parties to follow and participate in that proceeding to assist TSA in developing reasonable, accurate fees.

TSA is adding a new paragraph (g) to this section in response to comments received from State DMVs and individual drivers concerning HME transfers. Pursuant to the FMCSA rules, drivers who change their State of residence must register with the new State of residence within 30 days and apply for a transfer HME. 49 CFR 383.71(b). Drivers and the DMV offices questioned whether a new security threat assessment is necessary each time a driver moves to another State, regardless of when the previous threat assessment occurred. TSA agrees that requiring a new threat assessment each time a driver moves is burdensome and unnecessary. Therefore, the rule now permits a transferring HME holder to forego a new security threat assessment in the new State of residence until the

renewal period established in the preceding issuing State expires.

Paragraph (h) provides that each State must retain all applicant information collected for the security threat assessment for at least one year. TSA believes this requirement is necessary to ensure that the information is available if questions or appeals arise in the course of the security threat assessment. The States, as licensing bodies, currently keep some of this information now as part of the commercial drivers license and HME program. The State may keep this information in paper or electronic form.

Section 1572.15 Procedures for Security Threat Assessment

This section describes the security threat assessment process in detail, and provides that no State can issue an HME unless the steps outlined in this section have been completed. The process includes the fingerprint-based check, an intelligence-related check, and a final disposition.

The fingerprint-based check covers an individual's criminal history to determine whether the applicant has been convicted of or incarcerated for a disqualifying felony under Federal, State, or local law. In addition, TSA can review databases related to an applicant's dishonorable discharge from the armed service, if any, during this phase of the security threat assessment, which may indicate whether the applicant has a disqualifying military conviction. This check requires collecting fingerprints and applicant information, and submitting the prints to the FBI and the information to TSA.

The intelligence-related check involves the use of an applicant's biographical and identification information that is collected during the HME application process. This check searches for potential terrorist activity, immigration status, and mental incompetency. In many cases, only certain Federal agencies are authorized to access the pertinent databases to complete these checks, and some of these databases may be classified.

Once TSA has received the results of the fingerprint- and intelligence-related checks, TSA reviews them to determine if the individual meets the security threat assessment standards. If the applicant meets the standards, TSA will notify the State with a Determination of No Security Threat for the applicant. Once the State receives this Determination, it issues or renews the HME.

If TSA determines that an applicant does not meet the standards for holding an HME, TSA issues an Initial Determination of Threat Assessment to the applicant. The Initial Determination includes the basis for the determination; instructions on how the individual may appeal the finding; and a statement that if the applicant does not appeal the finding, the Initial Determination becomes a Final Determination of Threat Assessment, which cannot be appealed. If the applicant does not appeal the finding, TSA notifies the issuing State, and the State cannot issue, renew, or transfer the applicant's HME.

If an applicant appeals the Initial Determination, but the appeal does not overturn the Initial Determination, TSA notifies the State and applicant with a Final Determination of Threat Assessment. However, if TSA determines that the Initial Determination was inaccurate (due to incomplete court records, for instance) and grants the appeal, TSA issues a Withdrawal of the Initial Determination of Threat Assessment to the applicant and a Determination of No Security Threat to the State.

This IFR now includes details of the process involved when an immediate revocation occurs. The State must immediately revoke an HME when so notified by TSA. TSA will issue an Initial Determination of Threat Assessment and Immediate Revocation when TSA's security threat assessment indicates that a driver may pose an imminent threat to national or transportation security. This issuance may also occur when an individual has a disqualifying offense, but has not surrendered his endorsement, as required by the rule. Under this procedure, the individual's HME is revoked immediately and he may appeal the revocation afterward. Also, if TSA does not receive an appeal of an Initial Determination of Threat Assessment and Immediate Revocation within the prescribed time periods, the Initial Determination becomes final. If TSA grants the appeal, TSA will issue a Withdrawal of the Initial Determination to the applicant and Determination of No Security Threat to the State.

It is important to note that TSA may begin the final disposition phase of the threat assessment process after receiving adverse information from the fingerprint- or intelligence-related portion of the check, even if both checks are not complete. For instance, if TSA obtains the results of an intelligence-related check before the fingerprint-based check, and the information identifies the applicant as a terrorist, TSA may issue its Initial and Final Determinations before the fingerprint check is complete. There is no reason to wait for all information to become available if the information in hand is disqualifying. We do not anticipate that this scenario will occur often.

An applicant may appeal an adverse finding due to the fingerprint- or the intelligence-related checks. This process will often be a ''correction of records'' because the basis of the appeal is that the records on which TSA relied are not accurate or involve a different individual. In the case of an appeal of the intelligence-related check, the data or documents that gave rise to the adverse finding may be classified or otherwise protected by law, in which case TSA cannot release the document or information. However, TSA will make every effort to provide as much information to the applicant as the law permits to facilitate a meaningful appeal.

Certain applicants disqualified from holding an HME may request a waiver of the standards. Individuals who commit certain disqualifying offenses or have a history of mental incapacity are eligible to apply for a waiver. Individuals identified as posing a threat under § 1572.107 or do not fall within the lawful immigration categories listed in the IFR are not eligible for a waiver.

TSA uses the term ''serves'' in the rule text for the process by which TSA will notify the States and applicants of the security threat assessment determinations. The definition of ''date of service'' in § 1572.3 includes the date of personal delivery; the mailing date shown on a certificate of service; 10 days from the date of mailing if there is no certificate of service; another mailing date shown by other evidence if there is no certificate of service or postmark; or the date on which an electronic transmission is sent.

TSA and the States have discussed the benefits of communicating this sort of information electronically, and so ''serve'' may include uploading the notifications to the State on a secure website. This method of communication would save time, paper, and money, and furthers the e-government movement. However, there may be instances in which a State would prefer to receive a determination in hard copy, and so TSA invites comment from the States on this issue.

TSA has some concern about the potential difficulty in providing notice to a driver who may be on the road for weeks at a time. The information required in § 1572.9 requests the applicant's mailing address if it differs from the residential address. Drivers should be careful when completing the application to provide the address that is best for appropriate notice from the State and TSA. We have amended the

definition of ''date of service'' to underscore that TSA will use the address given on the application for service of documents. We invite comment on this issue from drivers and their associations as to how this concern can be minimized.

Once the fingerprint- and intelligence-related checks are complete, paragraph (d) explains the actions TSA will take to conclude the assessment.

Section 1572.103 Disqualifying Criminal Offenses

Congress did not specify in the USA PATRIOT Act the criminal offenses that TSA must use to determine whether a person poses a security risk warranting denial of an HME. TSA considered the crimes listed in 49 U.S.C. 44936, which include misdemeanors and felonies, for individuals who have unescorted access to secured areas of airports or aircraft, security screeners, and other aviation personnel.

However, TSA included only felonies, and felonies that constitute the most serious crimes as disqualifying. The list includes crimes that demonstrate an individual's willingness to commit violent acts against others for personal reasons, such as murder or assault with intent to murder. The list also includes the crime of smuggling contraband. TSA is concerned with the possibility that such an individual could be involved intentionally, or may be used unwittingly by others with malicious intent, in transporting items that could be used to commit terrorist acts. The listed offenses are considered grounds for disqualification whether they are prosecuted by civilian or military authorities. If an applicant has a disqualifying criminal offense, but believes that under the particular circumstances of the offense the applicant should not be determined to pose a security threat, the applicant may request a waiver under § 1572.143.

This IFR makes changes to the Current Rule's list of crimes that disqualify an applicant for life from holding an HME. The Current Rule lists espionage, sedition, treason, arson, crimes involving a transportation security incident, improper transportation of a hazardous material under 49 U.S.C. 5124, any crime listed in 18 U.S.C. chapter 113B—Terrorism, and conspiracy or attempt to commit the crimes in paragraph 1572.103(a) as permanently disqualifying. TSA is reclassifying arson as an interim rather than permanent disqualifying offense. As discussed in greater detail above, TSA has concluded that an arson conviction does not typically present the same level of threat as a conviction for treason or espionage and is more analogous to the interim disqualifying offenses. Also, the IFR now makes a RICO conviction based on an underlying permanent disqualifying offense a permanently disqualifying offense. The Current Rule lists as permanently disqualifying the ''unlawful possession, use, sale, distribution, or manufacture of an explosive.'' We now add ''purchase, receipt, transfer, shipping, transporting, delivery, import, export of, or dealing in an explosive or explosive device'' to this list, because these additional actions regarding explosives are equally serious. TSA is reclassifying murder as a permanent rather than interim disqualifying offense. We believe it is more analogous to the other permanently disqualifying offenses in terms of the security threat it presents.

Under the Current Rule, individuals who have been convicted within the preceding seven years of, or incarcerated within the preceding five years for a criminal offense listed in § 1572.103(b), are disqualified until the seven- or five-year time period ends, whichever is later. In the Current Rule, the offenses in paragraph 1572.103(b) are murder; assault with intent to murder; kidnapping or hostage taking; rape or aggravated sexual abuse; unlawful possession, use, sale, purchase, distribution, or manufacture of a firearm or other weapon; extortion; dishonesty, fraud, or misrepresentation, including identity fraud; bribery; smuggling; immigration violations; violations of the Racketeer Influenced and Corrupt Organizations Act; 18 U.S.C. 1961, *et seq.*; robbery; and distribution of, intent to distribute, or importation of a controlled substance.

This IFR amends the list of interim disqualifying offenses in several ways. The Current Rule lists as disqualifying the ''unlawful possession, use, sale, distribution, or manufacture of a firearm or other weapon.'' We now add ''purchase, receipt, transfer, shipping, transporting, delivery, import, export of, or dealing in a firearm or other weapon'' to this list, because these additional actions regarding a weapon are equally serious. Second, we are removing ''simple possession'' of a controlled substance as disqualifying and making clear that ''possession with intent to distribute a controlled substance'' remains a disqualifying offense. TSA makes this change to ensure that only the most serious offenses, including those demonstrating a willingness to endanger others, are considered disqualifying. TSA is reclassifying arson as an interim rather than permanent disqualifying offense, as it is in the Current Rule. Finally, TSA is reclassifying murder as a permanently rather than interim disqualifying offense.

We note, as discussed when this rule first was adopted, that this rule cannot possibly list all of the offenses or other information that may be relevant to determining whether an individual poses a security threat that merits denial of a hazardous materials endorsement. Therefore, under § 1572.107, TSA may consider other criminal offenses and information not listed in § 1572.103, if they indicate the individual poses a security threat. TSA believes these changes in § 1572.107 clarify the extent of TSA's discretion. See 68 FR 23852 at 23861 col. 2–3.

TSA invites comment from all interested parties concerning this list of disqualifying criminal offenses. TSA must balance its responsibility to enhance the security of hazardous materials transportation against the knowledge that individuals who participate in criminal acts may subsequently become valuable members of the workforce. TSA wishes to minimize the adverse impact this program may have on individuals who have committed criminal offenses and served their sentences, without compromising the security of hazardous materials in transportation. Therefore, with limited exceptions, only convictions within the seven years prior to the date of the application to apply or renew a hazardous materials endorsement, or incarcerations that ended within five years prior to the date of application, will disqualify an individual. This approach is consistent with the requirements of MTSA.

Paragraph (c) states that an applicant who is under a want or warrant for any of the disqualifying offenses is disqualified until the want or warrant is released. TSA will adjudicate these cases and notify appropriate law enforcement agencies and the State. TSA will review the want and warrant records carefully to determine the nature of the charge, and if it does not involve a disqualifying offense, but is indicative of a serious criminal act, TSA may notify law enforcement pursuant to § 1572.107, discussed below.

Paragraph (d) describes how an arrest with no indication of a conviction, plea, sentence or other information indicative of a final disposition must be handled. The individual must provide TSA with written proof that the arrest did not result in a disqualifying criminal offense within 45 days after the date TSA notifies the individual. If TSA does not receive such proof in 45 days, TSA will notify the applicant and the State that

the applicant is disqualified from holding an HME.

Section 1572.105 Immigration Status

The USA PATRIOT Act and SEA require a check of the relevant databases to determine the applicant's status under U.S. immigration laws prior to authorizing the applicant to transport hazmat. In addition, longstanding rules concerning the qualifications needed to hold a CDL provide that the driver must have a State of domicile in the United States or hold a nonresident CDL.[22] The Current Rule requires applicants for an HME security threat assessment to be U.S. citizens or lawful permanent residents. As discussed in greater detail above, in this IFR, TSA expands the group eligible to apply for an HME security threat assessment to include individuals who are qualified to hold a CDL, but who are not U.S. citizens or lawful permanent residents. This group includes nonimmigrant aliens, asylees, and refugees, who are in lawful status and possess valid and unrestricted documentation establishing eligibility for employment. These changes are reflected in paragraph (a) of this section. TSA is making one additional change to paragraph (a)(1) of this section by adding that an applicant must be a citizen who has not renounced ''or lost'' his or her citizenship. TSA is adding this language to cover instances in which a citizen is stripped of U.S. citizenship, as is the case with Nazi war criminals. It is unlikely that this situation will arise in the context of hazmat drivers, but TSA wishes to make certain that the rule covers instances in which it does occur.

To determine an individual's immigration status, TSA checks the relevant immigration databases, and may perform other checks, including verifying the applicant's identity and Social Security Number.

Section 1572.107 Other Analyses

Section 1012 of the USA PATRIOT Act requires background checks of relevant international databases, such as Interpol-U.S. National Central Bureau, or other appropriate sources. TSA checks these databases and other databases that include information on terrorists and terrorist activity, violent gangs, fugitives from justice, and international criminal records. TSA may also check databases that assist in confirming an individual's identity. This IFR provides that TSA will check the following databases, and conduct a security threat analysis, before determining whether an individual poses a security threat: (1) Interpol and other international databases as appropriate; (2) terrorist watchlists and related databases; and (3) other databases relevant to determining whether an individual may pose or poses a security threat or that confirm an individual's identity.

New paragraph (c) also states that TSA may determine that an individual poses a security threat if the search TSA conducts under part 1572 reveals an extensive or very serious domestic or foreign criminal history, conviction for serious crimes not listed in § 1572.103, or an extensive period of imprisonment, foreign or domestic, exceeding 365 consecutive days. TSA is adding this language to the rule text to clarify the full application of this section and to provide sufficient notice to the public that there may be cases in which an applicant's criminal record includes convictions for serious crimes that are not specifically listed in § 1572.103, but may be disqualifying. Also, if an applicant has been imprisoned for more than a year, which is generally indicative of a serious offense or a long history of criminal activity, TSA may determine that the applicant poses an unacceptable security threat. We use the term ''imprisoned'' in the new language, which is indicative of a more serious criminal sentence; time sentenced to a half-way house or treatment facility is not used to calculate the period of ''imprisonment,'' as it is with respect to ''incarceration.''

As TSA noted in the May 5 IFR, we cannot possibly list all of the offenses or other information that may be relevant to determining whether an individual poses a security threat that warrants denial of a hazardous materials endorsement. The preamble of the May 5 IFR stated that, under § 1572.107, TSA may consider other criminal offenses and information not listed in § 1572.103, if they indicate the individual poses a security threat. See 68 FR 23852 at 23861. The rule text for § 1572.107 clearly states this authority. TSA believes we must have a level of discretion to carry out the intent of the USA PATRIOT Act and responsibly assess threats to transportation and the Nation, where the intelligence and threats are so dynamic. TSA understands that the flexibility this language provides must be used cautiously and on the basis of compelling information that can withstand judicial review. TSA invites comment on this section.

Section 1572.109 Mental Capacity

The explosives laws prohibit individuals who have been adjudicated as lacking mental capacity (''mental defect'' is used in the statutory language, but we use ''lacking mental capacity'' in the IFR because it is less pejorative, but has and is intended to have the same meaning) from transporting explosives. This IFR will implement this requirement by providing that any person who has been determined to lack mental capacity does not meet the standards for a security threat assessment. This section adopts the terms and standards concerning individuals with mental disabilities promulgated by ATF:

> The legislative history of the GCA [Gun Control Act of 1968] makes it clear that a formal adjudication or commitment by a court, board, commission or similar legal authority is necessary before firearms disabilities are incurred. H.R. Rep. 1956, 90th Cong., 2d Sess. 30 (1968). The plain language of the statute makes it clear that a formal commitment, for any reason, *e.g.*, drug use, gives rise to firearms disabilities. However, the mere presence of a person in a mental institution for observation or a voluntary commitment to a mental hospital does not result in firearms disabilities.[23]

ATF also cited several cases in which courts held that the GCA was designed to prohibit the receipt and possession of firearms by individuals who are potentially dangerous, including individuals who are mentally incompetent or afflicted with a mental illness, and individuals found not guilty by reason of insanity in a criminal case.[24] Finally, ATF added to the definition of ''adjudicated as mental defective'' an element from the Department of Veterans Affairs definition of ''mental incompetent'' an individual who because of injury or disease lacks the mental capacity to contract or manage his or her own affairs.[25]

An individual lacks mental capacity, for purposes of this IFR, if he or she has been committed to a mental institution or has been adjudicated as lacking mental capacity. An individual is adjudicated as lacking mental capacity if a court or other appropriate authority determines that the individual is a danger to himself or herself, or lacks the mental capacity to manage his or her affairs. An individual is ''committed to an institution'' if formally committed by a court; this term does not refer to voluntary admissions to a mental institution or hospital. This standard is in the Current Rule and the IFR.

[22] 49 CFR 384.212.

[23] 61 FR 47095, September 6, 1996.

[24] *Id.*

[25] *Id.*

Section 1572.111–1572.139 [Reserved]

Section 1572.141 Appeal Procedures

An individual may appeal an Initial Determination of Security Threat if he asserts that he meets all standards for the security threat assessment. For example, if the Initial Determination was based on information indicating that the applicant is an alien who is not in the United States lawfully, the applicant may provide TSA with evidence that the immigration record is inaccurate in an appeal.

An applicant initiates an appeal by providing TSA with a written request for the releasable materials upon which the Initial Determination was based, or by serving TSA with his or her written reply to the Initial Determination. If an applicant wishes to receive copies of the releasable material upon which the Initial Determination was based, he must serve TSA with a written request within 30 days after the date of service of the Initial Determination. TSA's response is due within 30 days. In response, TSA cannot provide any classified information, as defined in Executive Order (E.O.) 12968, or any other information or material protected from disclosure by law.

If an applicant wishes to reply to the Initial Determination, he or she must provide TSA with a written reply no later than 30 days after the date of service of the Initial Determination or the date of service of TSA's response to the applicant's request for materials. The applicant should explain why he or she is appealing the Initial Determination and provide evidence that the Initial Determination was incorrect. In an applicant's reply, TSA will consider only material that is relevant to whether he or she meets the standards for the security threat assessment. If an applicant does not dispute or reply to the Initial Determination, the Initial Determination becomes a Final Determination.

Under paragraph (c)(3) of this section, an applicant has the opportunity to correct a record on which an adverse decision is based. So long as the record is not classified or protected by law from release, TSA will notify the applicant of the adverse information and provide a copy of the record. If the applicant wishes to correct the inaccurate information, he or she must provide written proof that the record is inaccurate. The applicant should contact the jurisdiction responsible for the inaccurate information to complete or correct the information contained in the record. The applicant must provide TSA with the revised record or a certified true copy of the information from the appropriate entity before TSA can reach a determination that the applicant does not pose a security threat that warrants denial of the HME.

The Director will make the Final Determination on appeals that involve disqualifying criminal offenses, mental capacity, and immigration status. However, in a case where an Initial Determination of Threat Assessment is based on the applicant's connection to terrorist activity or similar threat under § 1572.107, the Assistant Secretary will review the appeal and make the Final Determination. This procedure is a change from the Current Rule that TSA believes is necessary to provide additional scrutiny for cases that will likely involve a review of classified information that the applicant is not permitted to see under law. In addition, the applicant in these cases is not eligible for a waiver of the standards if the Initial Determination stands. TSA believes that the review by the Assistant Secretary for these cases provides an additional protection that the agency's Final Determination is sound.

In considering an appeal, the Director or Assistant Secretary will review the Initial Determination, the materials upon which the Initial Determination is based, the applicant's reply and any accompanying information, and any other materials or information available to TSA. The Director or Assistant Secretary may affirm the Initial Determination by concluding that an individual poses a security threat. In this case, TSA serves a Final Determination of Threat Assessment on the applicant. The Final Determination includes a statement that the Director or Assistant Secretary has reviewed the Initial Determination, the materials upon which the Initial Determination was based, the reply, if any, and any other materials or information available to the Director or Assistant Secretary and has determined that the applicant poses a security threat. There is no administrative appeal of the Final Determination of Threat Assessment. However, as explained below, an applicant may apply for a waiver under certain circumstances. For purposes of judicial review, the Final Determination of Threat Assessment constitutes a final TSA order.

Paragraph (e) sets forth the procedures to follow if TSA determines that the applicant does not pose a security threat. TSA serves a Withdrawal of the Initial Determination on the applicant and a Determination of No Security Threat on the issuing State.

If TSA did not serve the individual with an Initial Determination of Threat Assessment, or grants a waiver, the agency will transmit a Determination of No Security Threat to the applicant and the State in which the applicant applied for the HME.

Paragraph (f) provides that TSA cannot disclose classified information, as defined in E.O. 12968 section 1.1(d), to the applicant, and TSA reserves the right not to disclose any other information or material not warranting disclosure or protected from disclosure under law, such as Sensitive Security Information (SSI); sensitive law enforcement and intelligence information; sources, methods, means, and application of intelligence techniques; and identities of confidential informants, undercover operatives, and material witnesses.

For determinations under § 1572.107, the finding that an individual poses a security threat will be based, in large part, on classified national security information, unclassified information designated as SSI, or other information that is protected from disclosure by law.

Classified national security information is information that the President or another authorized Federal official has determined, pursuant to E.O. 12968, must be protected against unauthorized disclosure to safeguard the security of American citizens, the country's democratic institutions, and America's participation within the community of nations.[26] Executive Order 12968 prohibits Federal employees from disclosing classified information to individuals who have not been cleared to have access to such information under the requirements of that Executive Order.[27] If the Director determines that an applicant who is appealing the intelligence-related check is requesting classified materials, the applicant will not be able to access classified national security information, and TSA has no authority to release this information to the applicant.

The denial of access to classified information under these circumstances is consistent with the treatment of classified information under the Freedom of Information Act (FOIA), which specifically exempts such information from the general requirement under FOIA that all government documents are subject to public disclosure.[28]

SSI is unclassified information that is subject to disclosure limitations under statute and TSA regulations.[29] Under 49

[26] *See* E.O. 12958, 60 FR 19825, April 20, 1995.

[27] *See* E.O. 12968, sec. 3.2(a), 6.2(a)(1), 60 FR 40245, Aug. 7, 1995.

[28] *See* 5 U.S.C. 552(b)(1).

[29] *See* 49 U.S.C. 114(s); 49 CFR part 1520 as amended by 69 FR 28066 (May 18, 2004).

U.S.C. 114(s), the Assistant Secretary of TSA may designate categories of information as SSI if release of the information would be detrimental to the security of transportation. Information that is designated as SSI must only be disclosed to people with a need to know, such as those needing to carry out regulatory security duties.[30]

The Assistant Secretary has defined information concerning threats against transportation as SSI by regulation.[31] Thus, information that TSA obtains indicating that an applicant poses a security threat, including the source of such information and the methods through which the information was obtained, will commonly be designated SSI or classified information. The purpose of designating this information as SSI is to ensure that those who seek to do harm to the transportation system and their associates do not obtain access to information that will enable them to evade the government's efforts to detect and prevent their activities. Disclosure of this information, especially to an applicant specifically suspected of posing a threat to the transportation system, is precisely the type of harm that Congress sought to avoid by authorizing the Assistant Secretary to define and protect SSI.

Other pieces of information also are protected from disclosure by law due to their sensitivity in law enforcement and intelligence. In some instances, the release of information about a particular individual or his or her supporters or associates could have a substantial adverse impact on security matters. The release by TSA of the identities or other information regarding individuals related to a security threat determination could jeopardize sources and methods of the intelligence community, the identities of confidential sources, and techniques and procedures for law enforcement investigations or prosecution.[32] Release of such information also could have a substantial adverse impact on ongoing investigations being conducted by Federal law enforcement agencies, by revealing the course and progress of an investigation. In certain instances, release of information could alert co-conspirators to the extent of the Federal investigation and the imminence of their own detection, thus provoking flight.

For the reasons discussed above, TSA will not provide any classified information to an applicant, and TSA reserves the right to withhold SSI or other sensitive material protected from disclosure under law. As noted above, TSA expects that information will be withheld only for determinations based on § 1572.107, which involve databases that list indicators of potential terrorist activity or threats. When the determination is based on the individual's criminal records, TSA expects that appropriate supporting records most likely can be disclosed to the applicant upon a written request to TSA. With respect to disqualifications based on immigration status, TSA will provide the driver with the reason for a denial, but may not be able to provide specific documentation on the applicant's alien status.

Under this IFR, TSA has the discretion to extend due dates both for an applicant and for the agency during the appeal process. An applicant must provide a written statement of good cause for extending the due date, within a reasonable time prior to the due date at issue. TSA has changed this section from ''within seven days'' to a ''reasonable time'' to provide the driver as much time as he or she reasonably needs. This change is also in line with the rules of civil procedure. TSA anticipates that if an applicant is attempting to correct erroneous records or gather documents in support of a waiver request, the individual may need additional time for the appropriate governmental agency or entity to produce the documents. As long as the applicant provides a sufficient explanation of these problems, TSA will likely extend the time needed to complete the process.

Paragraph (i) of this section describes the procedure for appealing an immediate revocation of an HME under § 1572.13(a). Immediate revocation will occur where TSA determines during the course of conducting a security threat assessment that sufficient factual and legal grounds exist to warrant immediate revocation of the HME. Under these circumstances, the applicant must surrender the endorsement and cease transporting hazardous materials prior to initiating an appeal. TSA understands that removing the individual from service without an opportunity to correct the record may have adverse consequences, but this mechanism will be used only in cases where the risk of imminent danger is significant and the adverse information is highly reliable. This procedure will also be used where a driver should have surrendered the endorsement and/or applied for a waiver, but failed to do so. The individual may appeal this decision, must include all supporting documentation when he or she submits the appeal, and may request releaseable documents from TSA.

Section 1572.143 Waiver Procedures

This section applies to applicants who have been disqualified from holding or obtaining an HME due to a disqualifying criminal offense or mental incompetency. The Current Rule provides that an applicant with any disqualifying offense or issues of mental competence may apply for a waiver. In this IFR, TSA prohibits applicants with certain criminal convictions from applying for a waiver. TSA has concluded that crimes of espionage, treason, sedition, a terrorist act, or a crime involving a transportation security incident are so highly indicative of a security threat that individuals convicted of them pose an ongoing, unacceptable risk to transportation security. Most likely, these individuals will be incarcerated for a very long term, but the rule now makes clear that convictions for these crimes disqualify an individual for life, with no opportunity to apply for a waiver. Individuals who are disqualified due to mental incompetence continue to be eligible for a waiver.

Waivers are offered because an applicant may be rehabilitated to the point that he or she can be trusted in sensitive or potentially dangerous work or has been declared mentally competent. The Current Rule and this IFR provide criteria that TSA considers if the individual does not meet the criminal history standards. TSA believes that these factors are good indicators that an individual may be rehabilitated to the point that a waiver is advisable. The factors are: (1) The circumstances of the disqualifying act or offense; (2) restitution made by the individual; (3) Federal or State mitigation remedies; (4) court records indicating that the individual has been declared mentally competent; and (5) other factors TSA believes bear on the potential security threat posed by the individual. Many of these factors are set forth in MTSA, at 46 U.S.C. 70105(c)(2).

With respect to mental competency, TSA will accept a court order or official medical declaration showing that an individual previously declared incompetent is now competent to support the waiver request. Generally, TSA will not grant waivers on the basis of a letter from a treating physician stating that the individual is capable of maintaining a job, because these submissions tend to be very subjective and vague. The standard in the rule states that an applicant is mentally

[30] *See* 49 CFR 1520.11 as added by 69 FR 28084–5.

[31] *See* 49 CFR 1520.5

[32] *See* 5 U.S.C. 552(b)(7)(D), (E).

incompetent if a court declares it or he or she is involuntarily committed to a mental hospital. Official documents that reverse these findings are necessary for TSA to grant a waiver. TSA requests comment on any additional criteria that the agency should consider when determining whether to grant a waiver.

TSA, however, will not grant waivers from the standards concerning immigration status or information discovered during a search under § 1572.107. With respect to immigration violations and findings under § 1572.107, individuals may appeal an Initial Determination based on assertions that the underlying records are incorrect, the applicant's identity is mistaken, or TSA's analysis of the records is not correct. However, if TSA finds that the Initial Determination is accurate, the individual is ineligible for a waiver.

After reviewing an individual's application for a waiver, TSA sends a written decision to the individual and, if the waiver is granted, a Determination of No Security Threat to the State in which the individual applied for the HME within 30 days after the date of the individual's waiver application.

Subpart C—Transportation of Explosives From Foreign Locations

In this IFR, TSA moves the existing standards concerning the transportation of explosives from Canada to the United States via commercial motor vehicle and rail to new subpart C. The existing standards are not changing substantively; they are just being moved to a separate Subpart.

Rulemaking Analyses and Notices

Justification for Immediate Adoption

TSA is issuing this interim final rule without prior notice and opportunity to comment on certain new standards, pursuant to authority under section 4(a) of the Administrative Procedure Act (5 U.S.C. 553(b)). This provision allows the agency to issue a final rule without notice and opportunity to comment when the agency for good cause finds that notice and comment procedures are ''impracticable, unnecessary or contrary to the public interest.''

TSA issued the May 5 IFR and request for comments that set forth most of the standards that are in the document we publish today. TSA received comments from the States and the trucking industry, and to the extent possible, we now make changes to the rule to accommodate those comments. However, certain details of the program implementation were not available to TSA when the Current Rule was published. The full program will become operational on January 31, 2005, and the States must have this information as soon as possible in order to implement the program.

Also, TSA must determine quickly how many States will elect to collect fingerprints and applicant information and how many will opt to have TSA complete this work, so that TSA can procure a contractor to establish a national fingerprinting collection system. This document requires the States to make this declaration within 30 days of publication of the rule so that TSA can publish a request for proposals to implement the program.

Therefore, TSA believes that issuing a proposed rule to address the changes and new provisions in the rule is contrary to the public interest and impracticable. Most of the amendments we are making to the Current Rule are minor and actually reduce burdens on the States. We are issuing this IFR with a request for comments and will publish a discussion and resolution of all comments received, and make any needed changes to the rule.

Regulatory Evaluation

Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), provides for making determinations whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order.

TSA has determined that this action is a significant regulatory action within the meaning of Executive Order 12866 because there is significant public interest in security issues since the events of September 11, 2001, and approximately 2.7 million commercial drivers are subject to the rule. This IFR amends existing standards that implement section 1012 of the USA PATRIOT Act by establishing the criteria used in determining whether an individual applying for, transferring, or renewing an HME poses a security risk warranting denial of the endorsement. OMB has reviewed this rule.

TSA has prepared a detailed analysis of the costs and benefits of the hazmat security threat assessment program, which has been placed in the docket. A summary of that analysis is set forth below.

Costs

The IFR results in a cost impact for TSA, States, and individuals applying for, transferring, or renewing an HME. TSA will incur costs for conducting security threat assessments and for bringing on line the systems, personnel, and resources to conduct the security threat assessments. The major cost-related areas for the States are applicant information and fingerprint collection, processing, and transmission. Hazmat driver applicants will incur opportunity costs in complying with the requirements of the IFR.

Individuals applying for, transferring, or renewing an HME will incur opportunity costs in complying with the requirements of the IFR. These applicants will also have cash expenditures, or out-of-pocket costs, that would be approximately equal to the total of: (1) Fingerprint associated costs, (2) fees established to cover information and fingerprint collection and transmission, and (3) the fee established to cover the cost of security threat assessments. Because the aforementioned costs have been estimated separately in this analysis, no separate estimate was made for out-of-pocket Hazmat driver applicant costs. Rather, to avoid double counting these costs, TSA assumed that out-of-pocket Hazmat driver applicant expenses are accounted for in the separate estimates of fingerprinting and associated costs, information and fingerprint collection and transmission costs, and TSA security threat assessment costs.

For this cost analysis, three scenarios were considered: (1) All States choose to collect applicant information and fingerprints, (2) 50 percent of the States choose to collect information and fingerprints, and (3) all States choose to allow a TSA agent to collect information and fingerprints. TSA estimated the total ten-year undiscounted cost at $534.1 million under scenario 1, $532.3 million under scenario 2, and $530.5 million under scenario 3.

Table 1 summarizes the ten-year discounted and undiscounted costs of the IFR. Separate estimates of costs are shown for States and TSA (Federal government costs). Table 1 also shows discounted and undiscounted opportunity costs to Hazmat drivers based on the time that they must spend providing information and fingerprints.

TABLE 1.—OVERALL SUMMARY OF TEN-YEAR COSTS UNDER THREE SCENARIOS

[millions]

	All States collect applicant information		50% of States collect applicant information		All States choose TSA agent	
	Undiscounted costs	Present value	Undiscounted costs	Present value	Undiscounted costs	Present value
Population (renewals, transfers, new applicants)	4.1	.....	4.1	.....	4.1	.....
Federal (TSA) Costs:						
Start Up (non-recur)	$4.8	$4.8	$4.8	$4.8	$4.8	$4.8
Recurring Costs	130.6	98.2	130.6	98.2	130.6	98.2
FP and Associated Cost	0.0	0.0	116.1	87.3	232.2	174.5
Total States (2004–2013)	135.4	103.0	251.5	190.3	367.6	277.5
States Cost:						
Start Up (non-recur)	3.6	3.6	1.8	1.8	NA	NA
FP and Associated Cost	232.2	174.5	116.1	87.3	NA	NA
Recordkeeping	6.4	4.8	6.4	4.8	6.4	4.8
Total States (2004–2013)	242.2	182.9	124.3	93.9	6.4	4.8
Opportunity Costs:						
Lost Time	156.5	117.6	156.5	117.6	156.5	117.6
Total Cost Impact	534.1	403.5	532.3	406.5	530.5	399.9

Benefits

The primary benefit of the rule will be increased protection of property and citizens in the U.S. from acts of terrorism. Part of TSA's mission is to ensure the security of hazardous materials in transportation so that these materials are not used in an act of terrorism. The changes envisioned in this interim final rule are an integral part of the total program needed by the transportation industry to prevent such acts of terrorism.

When quantifying benefits for which there are no exact parallels, similar magnitude events can demonstrate the ranges of possible magnitudes for either costs or benefits. Two terrorist attacks on U.S. soil provide examples of the harm that can occur from explosive material delivered in a van or light truck: The 1993 New York World Trade Center (WTC) bombing and the 1995 Oklahoma City Federal Building bombing. The 1993 WTC bombing killed six people, injured over 1,000, and resulted in over $510 million in insured losses. The Oklahoma City (OKC) bombing killed 168 people, injured 601, and resulted in over $125 million in insured losses. Total losses for these incidents were estimated at $685 million.

The intent of the IFR is to limit access to hazardous material by persons viewed as a security threat. The rule is designed to decrease the probability of terrorist incidents related to Hazmat misuse. Although the 1993 WTC and 1995 OKC bombings were not executed by Hazmat drivers, these examples show the potential damage that can occur using a van or light truck. If larger vehicles were used to carry out a terrorist attack, the damage could be far greater.

The IFR would establish a level of security that would reduce the likelihood of such an event occurring. The prevention of just one terrorist attack similar to the examples above over the next 10 years would offset the cost of this rule, and supports the rule as cost-beneficial. In addition, there are other benefits associated with ripple effects of incidents of this magnitude. This type of multiplier effect is important in determining benefits.

Initial Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980, as amended, (RFA) was enacted by Congress to ensure that small entities (small businesses, small not-for-profit organizations, and small governmental jurisdictions) are not unnecessarily or disproportionately burdened by Federal regulations. The RFA requires agencies to review rules to determine if they have ''a significant economic impact on a substantial number of small entities.'' TSA has determined that this interim final rule will not have a significant economic impact on a substantial number of small entities.

Under the RFA, the term ''small entity'' has the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' This action will affect States, and States are governmental jurisdictions. However, States are not considered ''small governmental jurisdictions'' under the RFA. As defined by the RFA, small governmental jurisdictions include governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50 thousand.

The action would also affect individuals, but current industry practice is for individual drivers to obtain their CDL certification as a condition of employment. Individuals are required to have a current CDL with appropriate endorsements to be eligible for employment. This cost is an employment cost typically borne by the individual employee, but individuals are not considered small entities for purposes of the RFA. However, individuals who are independent truck drivers and owner-operators would be subject to the RFA. For these individuals, the IFR would impose costs for information collection and fees associated with background checks (a total of $57 per individual).

TSA estimates that the total cost for these individuals would be approximately $100 per individual once the TSA security threat assessment fee is established and opportunity costs are considered. These costs will be spread over a period of five years (incurred only during the 5-year renewal process). TSA does not consider these costs to be significant when compared to the total cost of maintaining and operating a truck and considering that they are spread over a 5-year period (incurred only during the 5-year renewal process). Therefore, the burden on small business

entities from this rule is expected to be *de minimis*.

TSA has conducted the required review of this rule pursuant to the RFA, 5 U.S.C. 605(b) and has determined that it will not have a significant impact on a substantial number of small entities. Accordingly, TSA certifies that this rule will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), a Federal agency must obtain approval from the Office of Management and Budget (OMB) for each collection of information it conducts, sponsors, or requires through regulations. This IFR contains information collection activities subject to the PRA. Accordingly, the following information requirements have been submitted to OMB for its review.

Title: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Driver's License.

Summary: TSA is amending standards for security threat assessments of individuals applying for, renewing, or transferring a hazardous materials endorsement (HME) for a commercial driver's license (CDL), which in addition to the information already collected by the States for the purpose of HME applications, will now include fingerprints, immigration status, mental competency, and criminal history information.

Use of: Truck drivers must complete an application and provide fingerprints to undergo a security threat assessment. In States that opt to collect applicant information and fingerprints, the States and local agencies will most likely collect this information when individuals apply for, renew, or transfer an HME. In States that opt to have TSA collect the application and fingerprints, the States will continue to have responsibility for retaining the information that TSA collects.

Respondents (including number of): The likely respondents to this information requirement are individuals applying for, renewing or transferring an HME and each of the 50 States and the District of Columbia, for a total pool of approximately 2.7 million respondents.

Frequency: Estimates indicate that approximately 2.7 million people have an HME and this number is expected to initially decrease for the first three years, then grow by approximately 1.0% per year for a ten-year total of approximately 2.1 million people (210,000 annualized). The number of fingerprint applications to be collected over a ten-year period is approximately 4.1 million (407,000 annualized). This number includes new applicants, transfers, and renewals. States must notify each HME holder of the requirement to undergo a security threat assessment at least 60 days prior to the expiration date of the endorsement.

Annual Burden Estimate: Fingerprint costs consist of a processing fee, processing time, and material. The average collection cost for the fingerprint process was estimated at approximately $35 per set. TSA estimates that it will take an average of thirty minutes to complete an FBI fingerprint card and forward it to the FBI for further processing. Individual respondents will also be required to complete an application to certify their immigration status, mental competency, and relevant criminal history. TSA estimates this form will take an average of thirty minutes to complete. Thus, for individuals, the annual estimated burden is 407,000 hours at a cost of $14.25 million. Added to these estimates will be an annual recordkeeping burden of 4,800 hours plus $500,000 in data retention and reporting costs for all 50 states and the District of Columbia combined. TSA welcomes comment from the public concerning these estimates.

The agency is soliciting comments to—

(1) Evaluate whether the information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who must respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Pursuant to the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection will be published in the **Federal Register** after OMB approves it.

Executive Order 13132 (Federalism)

Executive Order 13132 requires TSA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under the Executive Order, TSA may construe a Federal statute to preempt State law only where, among other things, the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.

This action has been analyzed in accordance with the principles and criteria in the Executive Order, and it has been determined that this Interim Final Rule does have Federalism implications or a substantial direct effect on the States. Under this rule, the States may choose to collect information and process fingerprints that will be the basis for TSA's security threat assessment. TSA will develop the detailed procedures for the program in consultation with the States.

TSA notes that FMCSA has communicated with the States on the requirements of the USA PATRIOT Act. The Assistant Administrator of FMCSA wrote to licensing officials in each State on October 31, 2001, briefly summarizing section 1012 of the USA PATRIOT Act, and asking them to continue issuing and renewing hazardous materials endorsements until the regulations implementing section 1012 were completed. Some States have already enacted legislation they consider necessary to carry out the mandates of section 1012.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires Federal agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million in any one year (adjusted for inflation with base year of 1995). Before promulgating a rule for which a written statement is needed, section 205 of the UMRA generally requires agencies to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows TSA to

adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the agency publishes with the final rule an explanation as to why that alternative was not adopted.

This action will require a State expenditure of less than $5.0 million in the first year of the recurring phase, regardless of whether it chooses to collect applicant information and fingerprints or allow a TSA agent to collect the required information. The ten-year State cost is estimated to range between $6.4 million and $242.2 million undiscounted, depending on the option selected by the State. Based on this estimate, TSA has determined that the action will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million in any one year.

Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. TSA will continue to consult with Mexico and Canada under the North American Free Trade Agreement to ensure that any adverse impacts on trade are minimized. This rule applies only to individuals applying for a State-issued hazardous materials endorsement for a commercial drivers license. Thus, TSA has determined that this rule will have no impact on trade.

Environmental Analysis

TSA has reviewed this action for purposes of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) and has determined that this action will not have a significant effect on the human environment. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this rulemaking action qualifies for a categorical exclusion. The FAA order continues to apply to TSA in accordance with the Homeland Security Act (Pub. L. 107–296), until DHS publishes its NEPA implementing regulations.

Energy Impact

The energy impact of this document has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Public Law 94–163, as amended (42 U.S.C. 6362). We have determined that this rulemaking is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 49 CFR Part 1572

Commercial drivers license, Criminal history records check, Explosives, Hazardous materials, Motor carriers, Motor vehicle carriers, Security measures, Security threat assessment.

The Amendments

■ In consideration of the foregoing, the Transportation Security Administration amends chapter XII of title 49, Code of Federal Regulations, as follows:

SUBCHAPTER D—MARITIME AND LAND TRANSPORTATION SECURITY

■ 1. Revise part 1572 to read as follows:

PART 1572—CREDENTIALING AND BACKGROUND CHECKS FOR LAND TRANSPORTATION SECURITY

Subpart A—Requirements To Undergo Security Threat Assessments

Sec.

1572.1 Applicability.
1572.3 Terms used in this part.
1572.5 Scope and standards for hazardous materials endorsement security threat assessment.
1572.7 Waivers of hazardous materials endorsement security threat assessment standards.
1572.9 Applicant information required for a security threat assessment for a hazardous materials endorsement.
1572.11 Applicant responsibilities for a security threat assessment for a hazardous materials endorsement.
1572.13 State responsibilities for issuance of hazardous materials endorsement.
1572.15 Procedures for security threat assessment.

Subpart B—Standards, Appeals, and Waivers for Security Threat Assessments

1572.101 Scope.
1572.103 Disqualifying criminal offenses.
1572.105 Immigration status.
1572.107 Other analyses.
1572.109 Mental capacity.
1572.111–1572.139 [Reserved]
1572.141 Appeal procedures.
1572.143 Waiver procedures.

Subpart C—Transportation of Explosives From Foreign Locations

1572.201 Transportation of explosives from Canada to the United States via commercial motor vehicle.
1572.203 Transportation of explosives from Canada to the United States via railroad carrier.

Authority: 49 U.S.C. 114, 5103a, 40113, 46105; 18 U.S.C. 842, 845.

Subpart A—Requirements To Undergo Security Threat Assessments

§ 1572.1 Applicability.

This part prescribes regulations for credentialing and security threat assessments for certain maritime and land transportation workers.

§ 1572.3 Terms used in this part.

For purposes of this part:

Adjudicate means to make an administrative determination of whether an applicant meets the standards in this part based on the merits of the issues raised.

Alien means any person not a citizen or national of the United States.

Alien registration number means the number issued by the United States Department of Homeland Security to an individual when he or she becomes a lawful permanent resident of the United States or attains other lawful, non-citizen status.

Applicant means an individual who is applying for a new, renewal, or transfer hazardous materials endorsement.

Assistant Secretary means Assistant Secretary for Homeland Security, Transportation Security Administration (Assistant Secretary), who is the highest ranking TSA official, or his or her designee, and who is responsible for making the final determination on the appeal of an intelligence-related check under this part.

Commercial drivers license (CDL) is used as defined in 49 CFR 383.5.

Convicted includes any plea of guilty or *nolo contendere*, or any finding of guilt, except when the finding of guilt is subsequently overturned on appeal, pardoned, or expunged. For purposes of this part, a conviction is expunged when the conviction is removed from the individual's criminal history record and there are no legal disabilities or restrictions associated with the expunged conviction, other than the fact that the conviction may be used for sentencing purposes for subsequent convictions. In addition, where an individual is allowed to withdraw an original plea of guilty or *nolo contendere* and enter a plea of not guilty and the case is subsequently dismissed, the individual is no longer considered to have a conviction for purposes of this part.

Date of service means—

(1) In the case of personal service, the date of personal delivery to the residential address listed on the application;

(2) In the case of mailing with a certificate of service, the date shown on the certificate of service;

(3) In the case of mailing and there is no certificate of service, 10 days from

the date mailed to the address designated as the mailing address on the application;

(4) In the case of mailing with no certificate of service or postmark, the date mailed to the address designated as the mailing address on the application shown by other evidence; or

(5) The date on which an electronic transmission occurs.

Day means calendar day.

Determination of No Security Threat means an administrative determination by TSA that an individual does not pose a security threat warranting denial of a hazardous materials endorsement.

Director means the officer designated by the Assistant Secretary to administer the appeal and waiver programs described in this part, except where the Assistant Secretary is specifically designated in this part to administer the appeal or waiver program. The Director may appoint a designee to assume his or her duties.

Endorsement is used as defined in 49 CFR 383.5.

Explosive or explosive device includes, but is not limited to, an explosive or explosive material as defined in 18 U.S.C. 232(5), 841(c) through 841(f), and 844(j), and a destructive device as defined in 18 U.S.C. 921(a)(4) and 26 U.S.C. 5845(f).

Final Determination of Threat Assessment means a final administrative determination by TSA, including the resolution of related appeals, that an individual poses a security threat warranting denial of a hazardous materials endorsement.

Final Disposition means the actions that must be taken following issuance of a Determination of No Security Threat, a Final Determination of Security Threat, or the grant of a waiver to ensure that a driver's record, a driver's endorsement, and the Commercial Drivers License Information System (CDLIS) accurately reflect the results of the fingerprint and intelligence-related checks.

Firearm or other weapon includes, but is not limited to, firearms as defined in 18 U.S.C. 921(a)(3) or 26 U.S.C. 5845(a) or items contained on the U.S. Munitions Import List at 27 CFR 447.21.

Hazardous material has the same meaning as defined in section 103 of the Hazardous Materials Transportation Act.

Hazardous materials endorsement (HME) means the authorization for an individual to transport hazardous materials in commerce, which must be indicated on the individual's commercial driver's license.

Imprisoned or imprisonment means confined to a prison, jail, or institution for the criminally insane, on a full-time basis pursuant to a sentence imposed as the result of a criminal conviction or finding of not guilty by reason of insanity. Time spent confined or restricted to a half-way house, treatment facility, or similar institution pursuant to a sentence imposed as the result of a criminal conviction or finding of not guilty by reason of insanity does not constitute imprisonment for purposes of this rule.

Incarceration means confined or otherwise restricted to a jail-type institution, half-way house, treatment facility, or another institution, on a full or part-time basis pursuant to a sentence imposed as the result of a criminal conviction or finding of not guilty by reason of insanity.

Initial Determination of Threat Assessment means an initial administrative determination by TSA that an individual poses or may pose a security threat warranting denial of a hazardous materials endorsement.

Initial Determination of Threat Assessment and Immediate Revocation means an initial administrative determination that an individual poses a security threat that warrants immediate revocation of an HME. Upon issuance of this document, the State must immediately revoke the hazmat endorsement.

Lawful permanent resident means an individual who has been lawfully admitted to the United States for permanent residence, as defined in 8 U.S.C. 1101.

Mental institution means a mental health facility, mental hospital, sanitarium, psychiatric facility, and any other facility that provides diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

Pilot State means a State which volunteers to begin the security threat assessment process prior to January 31, 2005.

Revoke means the process by which a State cancels, rescinds, withdraws, or removes a hazardous materials endorsement.

State means a State of the United States and the District of Columbia.

Transportation security incident means a security incident resulting in a significant loss of life, environmental damage, transportation system disruption, or economic disruption in a particular area, as defined in 46 U.S.C. 70101.

Withdrawal of Initial Determination of Threat Assessment is the document that TSA issues after issuing an Initial Determination of Security Threat, when TSA determines that the applicant does not pose a security threat warranting denial of a hazardous materials endorsement.

§ 1572.5 Scope and standards for hazardous materials endorsement security threat assessment.

(a) This subpart applies to—

(1) State agencies responsible for issuing an HME; and

(2) Applicants who are qualified to hold a commercial driver's license under 49 CFR parts 383 and 384, and are applying for a new, renewal, or transfer HME.

(b) In conducting the security threat assessment requirements in this part, the States and TSA use one or more of the following:

(1) An applicant's fingerprints.

(2) An applicant's name.

(3) Other identifying information.

(c) TSA has determined that an applicant does not pose a security threat warranting denial of an HME if:

(1) The applicant does not have a disqualifying criminal offense described in § 1572.103;

(2) The applicant meets the immigration status requirements described in § 1572.105;

(3) TSA conducts the analyses described in § 1572.107 and determines that the applicant does not pose a security threat; and

(4) The applicant has not been adjudicated as lacking mental capacity or committed to a mental institution, as described in § 1572.109.

(d) TSA may direct a State to revoke an individual's HME immediately if TSA determines during the security threat assessment that the individual poses an immediate threat to transportation security, national security or of terrorism.

(e) The regulations of the Federal Motor Carrier Safety Administration (FMCSA) provide that an applicant is disqualified from operating a commercial motor vehicle for specified periods if he or she has an offense that is listed in the FMCSA rules at 49 CFR 383.51. If records indicate that an applicant has committed an offense that would disqualify the applicant from operating a commercial motor vehicle under 49 CFR 383.51, TSA will not issue a Determination of No Security Threat until the State or the FMCSA determine that the applicant is not disqualified under that section.

§ 1572.7 Waivers of hazardous materials endorsement security threat assessment standards.

(a) An applicant may apply to TSA for a waiver of the standards described in § 1572.5, if the applicant—

(1) Has a disqualifying criminal offense described in paragraphs 1572.103(a)(5) through (a)(9), and paragraph 1572.103 (a)(10) if the underlying criminal offense is in paragraphs 1572.103 (a)(5) through (a)(9); or

(2) Has a disqualifying criminal offense described in § 1572.103(b); or

(3) Has a history of mental incompetence described in § 1572.109.

(b) [Reserved].

§ 1572.9 Applicant information required for a security threat assessment for a hazardous materials endorsement.

(a) For TSA to complete a security threat assessment, an applicant must supply the information required in this section when the applicant applies to obtain or renew a hazardous materials endorsement. When applying to transfer a hazardous materials endorsement, § 1572.13(g) applies.

(b) The application must include the following identifying information:

(1) Legal name, including first, middle, and last; any applicable suffix; and any other name used previously.

(2) Current mailing address and residential address if it differs from the mailing address; and the previous residential address.

(3) Date of birth.

(4) Social security number.

(5) Gender.

(6) Height, weight, hair and eye color.

(7) City, state, and country of birth.

(8) Immigration status and date of naturalization if the applicant is a naturalized citizen of the United States.

(9) Alien registration number.

(10) State of application, CDL number, and type of endorsement held.

(11) The name, telephone number, and address of the applicant's current employer(s).

(c) The application must include the disqualifying criminal offenses identified in § 1572.103.

(d) The application must include a statement, signature, and date of signature that the applicant:

(1) Was not convicted or found not guilty by reason of insanity of a disqualifying crime listed in § 1572.103(b) in a civilian or military jurisdiction during the 7 years before the date of the application;

(2) Was not released from incarceration in a civilian or military jurisdiction for committing a disqualifying crime listed in § 1572.103(b) during the 5 years before the date of the application;

(3) Is not wanted or under indictment in a civilian or military jurisdiction for a disqualifying criminal offense identified in § 1572.103;

(4) Was not convicted or found not guilty by reason of insanity of a disqualifying criminal offense identified in § 1572.103(a) in a civilian or military jurisdiction;

(5) Has not been adjudicated as lacking mental capacity or committed to a mental institution involuntarily;

(6) Meets the immigration status requirements described in § 1572.105;

(7) Has or has not served in the military, and if so, the branch in which he or she served, the date of discharge, and the type of discharge; and

(8) Has been informed that Federal regulations under § 1572.11 impose a continuing obligation to disclose to the State within 24 hours if he or she is convicted or found not guilty by reason of insanity of a disqualifying crime, or adjudicated as lacking mental capacity or committed to a mental institution, while he or she holds an HME.

(e) The application must include a statement reading:

Privacy Act Notice: Authority: The authority for collecting this information is 49 U.S.C. 114, 40113, and 49 U.S.C. 5103a. *Purpose:* This information is needed to verify your identity and to conduct a security threat assessment to evaluate your suitability for a hazardous materials endorsement for a commercial drivers license. Furnishing this information, including your SSN or alien registration number, is voluntary; however, failure to provide it will prevent the completion of your security threat assessment, without which you cannot be granted a hazardous materials endorsement. *Routine Uses:* Routine uses of this information include disclosure to the FBI to retrieve your criminal history record; to TSA contractors or other agents who are providing services relating to the security threat assessments; to appropriate governmental agencies for licensing, law enforcement, or security purposes, or in the interests of national security; and to foreign and international governmental authorities in accordance with law and international agreement.

The information I have provided on this application is true, complete, and correct to the best of my knowledge and belief and is provided in good faith. I understand that a knowing and willful false statement, or an omission of a material fact, on this application can be punished by fine or imprisonment or both (see section 1001 of Title 18 United States Code), and may be grounds for denial of a hazardous materials endorsement.

§ 1572.11 Applicant responsibilities for a security threat assessment for a hazardous materials endorsement.

(a) *Prohibitions.* An applicant does not meet the security threat assessment standards if he or she:

(1) Has a disqualifying criminal offense identified in § 1572.103, unless TSA grants a waiver under § 1572.143; or

(2) Does not meet the immigration status requirements identified in § 1572.105; or

(3) Has been notified by TSA that he or she poses a security threat under § 1572.107; or

(4) Has been adjudicated as lacking mental capacity or committed to a mental institution as described in § 1572.109, unless TSA grants a waiver under § 1572.143.

(b) *Surrender of endorsement.* If an individual is disqualified from holding an HME under paragraph (a) of this section, he or she must surrender the HME and notify TSA. Failure to surrender the HME and notify TSA may result in immediate revocation under § 1572.13(a) and/or civil penalties.

(c) *Continuing responsibilities.* An individual who holds an HME must surrender the HME and notify TSA within 24 hours, if he or she:

(1) Is convicted of, wanted, under indictment, or found not guilty by reason of insanity in a civilian or military jurisdiction for a disqualifying criminal offense identified in § 1572.103; or

(2) Is adjudicated as lacking mental capacity or committed to a mental institution as described in § 1572.109; or

(3) Renounces or loses U.S. citizenship; or

(4) Violates his or her immigration status and/or is ordered removed from the United States.

(d) *Submission of fingerprints.* (1) An applicant who has not already done so may submit fingerprints in a form and manner specified by TSA when a State revokes the applicant's HME under § 1572.13(a).

(2) When so notified by the State, an applicant must submit fingerprints and the information required in § 1572.9 in a form and manner specified by the State and TSA, when TSA requests it, or when the applicant applies to obtain or renew an HME. The procedures outlined in § 1572.13(g) apply to HME transfers.

(3) When submitting fingerprints and the applicant information required in § 1572.9, the applicant or the applicant's employer is responsible for the TSA fee and the FBI fee.

§ 1572.13 State responsibilities for issuance of hazardous materials endorsement.

(a) Each State must immediately revoke an individual's HME if TSA informs the State that the individual does not meet the standards for security threat assessment in § 1572.5 and issues an Initial Determination of Threat Assessment and Immediate Revocation.

(b) Beginning January 31, 2005 for new issuances, and May 31, 2005 for renewal or transfer issuances:

(1) No State may issue or renew a hazardous materials endorsement for a CDL unless the State receives a Determination of No Security Threat from TSA.

(2) Each State must notify each individual holding a hazardous materials endorsement issued by that State that he or she will be subject to the security threat assessment described in this part as part of an application for renewal of the endorsement, at least 60 days prior to the expiration date of the individual's endorsement. The notice must inform the individual that he or she may initiate the security threat assessment required by this section at any time after receiving the notice, but no later than 30 days before the expiration date of the individual's endorsement.

(3) No State may begin processing renewal or transfer applicants prior to March 31, 2005.

(c) Prior to January 31, 2005, as approved by TSA, a Pilot State may not revoke, issue, renew, or transfer a hazardous materials endorsement for a CDL unless the Pilot State—

(1) Collects the information required in § 1572.9;

(2) Collects and submits fingerprints in accordance with procedures approved by TSA; and

(3) Receives a Determination of No Security Threat or a Final Determination of Threat Assessment from TSA.

(d) The State that issued an endorsement may extend the expiration date of the endorsement for 90 days if TSA has not provided a Determination of No Security Threat or a Final Determination of Threat Assessment before the expiration date. Any additional extension must be approved in advance by the Director.

(e) Within 15 days of receipt of a Determination of No Security Threat or Final Determination of Threat Assessment from TSA, the State must—

(1) Update the applicant's permanent record to reflect:

(i) The results of the security threat assessment;

(ii) The issuance or denial of an HME; and

(iii) The new expiration date of the HME.

(2) Notify the Commercial Drivers License Information System operator of the results of the security threat assessment.

(3) Revoke or deny the applicant's HME if TSA serves the State with a Final Determination of Threat Assessment.

(f) On or before December 27, 2004, each State must submit a written declaration to TSA, which shall remain in effect until January 31, 2008, unless otherwise authorized by TSA, that states one of the following:

(1) The State elects to collect and submit applicant fingerprints and information, in accordance with the requirements of this part and applicable fingerprint submission standards of the FBI, and the associated TSA and FBI fees; or

(2) The State elects to have TSA/TSA agent collect and submit applicant fingerprints and information, in accordance with the requirements of this part and applicable fingerprint submission standards of the FBI, and the associated TSA and FBI fees. If TSA does not receive a written declaration from a State, TSA will assume responsibility for the collection and submission process.

(g) For applicants who apply to transfer an existing hazardous materials endorsement from one State to another, the second State will not require the applicant to undergo a new security threat assessment until the security threat assessment renewal period established in the preceding issuing State, not to exceed five years, expires.

(h) Each State must retain the application and information required in § 1572.9 for at least one year in paper or electronic form.

§ 1572.15 Procedures for security threat assessment.

(a) *Contents of security threat assessment.* The security threat assessment TSA completes includes a fingerprint-based criminal history records check, an intelligence-related background check, and a final disposition.

(b) *Fingerprint-based check.* In order to conduct a fingerprint-based criminal history records check, the following procedures must be completed:

(1) The State notifies the applicant that he or she will be subject to the security threat assessment at least 60 days prior to the expiration of the applicant's HME and that the applicant must begin the security threat assessment no later than 30 days before the date of the expiration of the HME.

(2) Where the State elects to collect fingerprints and applicant information under § 1572.13(f)(1), the State—

(i) Collects fingerprints and applicant information required in § 1572.9;

(ii) Provides the applicant information to TSA electronically, unless otherwise authorized by TSA;

(iii) Transmits the fingerprints to the FBI/CJIS in accordance with the FBI/CJIS fingerprint submission standards; and

(iv) Retains the signed application, in paper or electronic form, for one year and provides it to TSA if requested.

(3) Where the State elects to have TSA/TSA agent collect fingerprints and applicant information under § 1572.13(f)(2)—

(i) TSA provides a copy of the signed application to the State;

(ii) The State retains the signed application, in paper or electronic form, for one year and provides it to TSA if requested; and

(iii) TSA transmits the fingerprints to the FBI/CJIS in accordance with the FBI/CJIS fingerprint submission standards.

(4) TSA receives the results from the FBI/CJIS and adjudicates the results of the check in accordance with § 1572.103 and, if applicable, § 1572.107.

(c) *Intelligence-related check.* To conduct an intelligence-related check, the following procedures are completed:

(1) TSA reviews the applicant information required in § 1572.9;

(2) TSA searches domestic and international government databases described in §§ 1572.105, 1572.107, and 1572.109;

(3) TSA adjudicates the results of the check in accordance with §§ 1572.103, 1572.105, 1572.107, and 1572.109.

(d) *Final Disposition.* Following completion of the procedures described in paragraphs (b) and/or (c) of this section, the following procedures apply, as appropriate:

(1) TSA serves a Determination of No Security Threat on the State in which the applicant is authorized to hold an HME, if TSA determines that an applicant meets the security threat assessment standards described in § 1572.5.

(2) TSA serves an Initial Determination of Threat Assessment on the applicant if TSA determines that the applicant does not meet the security threat assessment standards described in § 1572.5. The Initial Determination of Threat Assessment includes—

(i) A statement that TSA has determined that the applicant poses or is suspected of posing a security threat warranting denial of the HME;

(ii) The basis for the determination;

(iii) Information about how the applicant may appeal the determination, as described in § 1572.141; and

(iv) A statement that if the applicant chooses not to appeal TSA's determination within 30 days after receipt of the Initial Determination, or does not request an extension of time within 30 days after receipt of the Initial Determination in order to file an appeal,

the Initial Determination becomes a Final Determination of Security Threat Assessment.

(3) TSA serves an Initial Determination of Threat Assessment and Immediate Revocation on the applicant and the State, if TSA determines that the applicant does not meet the security threat assessment standards described in § 1572.5 and may pose an imminent threat to transportation or national security, or of terrorism. The Initial Determination of Threat Assessment and Immediate Revocation includes—

(i) A statement that TSA has determined that the applicant poses or is suspected of posing a security threat warranting immediate revocation of an HME;

(ii) The basis for the determination;

(iii) Information about how the applicant may appeal the determination, as described in § 1572.141(i); and

(iv) A statement that if the applicant chooses not to appeal TSA's determination within 30 days after receipt of the Initial Determination and Immediate Revocation, the Initial Determination and Immediate Revocation becomes a Final Determination of Threat Assessment.

(4) TSA serves a Final Determination of Threat Assessment on the State in which the applicant applied for the HME and on the applicant, if the appeal of the Initial Determination results in a finding that the applicant poses a security threat.

(5) TSA serves a Withdrawal of the Initial Determination of Threat Assessment or a Withdrawal of Final Determination of Threat Assessment on the applicant and a Determination of No Security Threat on the State, if the appeal results in a finding that the applicant does not pose a threat to security, or if TSA grants the applicant a waiver pursuant to § 1572.143.

Subpart B—Standards, Appeals, and Waivers for Security Threat Assessments

§ 1572.101 Scope.

This subpart applies to applicants who hold or are applying to renew or transfer an HME.

§ 1572.103 Disqualifying criminal offenses.

(a) *Permanent disqualifying criminal offenses.* An applicant has a permanent disqualifying offense if convicted or found not guilty by reason of insanity in a civilian or military jurisdiction of any of the following felonies:

(1) Espionage.

(2) Sedition.

(3) Treason.

(4) A crime listed in 18 U.S.C. Chapter 113B—Terrorism, or a State law that is comparable.

(5) A crime involving a transportation security incident.

(6) Improper transportation of a hazardous material under 49 U.S.C. 5124 or a State law that is comparable.

(7) Unlawful possession, use, sale, distribution, manufacture, purchase, receipt, transfer, shipping, transporting, import, export, storage of, or dealing in an explosive or explosive device.

(8) Murder.

(9) Conspiracy or attempt to commit the crimes in this paragraph (a).

(10) Violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. 1961, *et seq.*, or a State law that is comparable, where one of the predicate acts found by a jury or admitted by the defendant, consists of one of the offenses listed in paragraphs (a)(4) or (a)(8) of this section.

(b) *Interim disqualifying criminal offenses.* The felonies listed in paragraphs (b)(1) through (b)(14) of this section are disqualifying if either of the following factors is true: the applicant was convicted or found not guilty by reason of insanity of the crime in a civilian or military jurisdiction, within the 7 years preceding the date of application; or the applicant was released from incarceration for the crime within the 5 years preceding the date of application.

(1) Assault with intent to murder.

(2) Kidnapping or hostage taking.

(3) Rape or aggravated sexual abuse.

(4) Unlawful possession, use, sale, manufacture, purchase, distribution, receipt, transfer, shipping, transporting, delivery, import, export of, or dealing in a firearm or other weapon.

(5) Extortion.

(6) Dishonesty, fraud, or misrepresentation, including identity fraud.

(7) Bribery.

(8) Smuggling.

(9) Immigration violations.

(10) Violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. 1961, *et seq.*, or a State law that is comparable, other than the violations listed in paragraph (a)(10) of this section.

(11) Robbery.

(12) Distribution of, possession with intent to distribute, or importation of a controlled substance.

(13) Arson.

(14) Conspiracy or attempt to commit the crimes in this paragraph (b).

(c) *Under want or warrant.* An applicant who is wanted or under indictment in any civilian or military jurisdiction for a felony listed in this section is disqualified until the want or warrant is released.

(d) *Determination of arrest status.* (1) When a fingerprint-based check discloses an arrest for a disqualifying crime listed in this section without indicating a disposition, TSA will so notify the applicant and provide instructions on how the applicant must clear the disposition, in accordance with paragraph (d)(2) of this section.

(2) The applicant must provide TSA with written proof that the arrest did not result in a disqualifying criminal offense within 45 days after the service date of the notification in paragraph (d)(1) of this section. If TSA does not receive proof in that time, TSA will notify the applicant and the State that the applicant is disqualified from holding an HME.

§ 1572.105 Immigration status.

(a) An applicant applying for a security threat assessment for an HME must be—

(1) A citizen of the United States who has not renounced or lost his or her United States' citizenship; or

(2) A lawful permanent resident of the United States, as defined in section 101(a)(20) of the Immigration and Nationality Act (8 U.S.C. 1101); or

(3) An individual who is—

(i) In lawful nonimmigrant status and possesses valid evidence of unrestricted employment authorization; or

(ii) A refugee admitted under 8 U.S.C. 1157 and possesses valid evidence of unrestricted employment authorization; or

(iii) An alien granted asylum under 8 U.S.C. 1158, and possesses valid evidence of unrestricted employment authorization.

(b) To determine an applicant's immigration status, TSA checks relevant Federal databases and may perform other checks, including verifying the validity of the applicant's social security number or alien registration number.

§ 1572.107 Other analyses.

(a) An applicant poses a security threat and is therefore disqualified under this section when TSA determines or suspects the applicant of posing a threat—

(1) To national security; or

(2) To transportation security; or

(3) Of terrorism.

(b) TSA checks the following databases and analyzes the resulting information before determining that an applicant does not pose a security threat warranting denial of an HME:

(1) Interpol and other international databases, as appropriate;

(2) Terrorist watchlists and related databases; and

(3) Any other databases relevant to determining whether an applicant poses or is suspected of posing a security threat, or that confirm an applicant's identity.

(c) TSA may determine that an applicant poses a security threat if the search conducted under this part reveals extensive foreign or domestic criminal convictions; a conviction for a serious crime not listed in § 1572.103, or a period of foreign or domestic imprisonment that exceeds 365 consecutive days.

§ 1572.109 Mental capacity.

(a) An applicant has lacking mental capacity if he or she has been—

(1) Adjudicated as lacking mental capacity; or

(2) Committed to a mental institution.

(b) An applicant is adjudicated as lacking mental capacity if—

(1) A court, board, commission, or other lawful authority has determined that the applicant, as a result of marked subnormal intelligence, mental illness, incompetence, condition, or disease, is a danger to him- or herself or others, or lacks the mental capacity to contract or manage his or her own affairs.

(2) This includes a finding of insanity by a court in a criminal case; and a finding of incompetence to stand trial or a finding of not guilty by reason of lack of mental responsibility by any court, or pursuant to articles 50a and 76b of the Uniform Code of Military Justice (10 U.S.C. 850a and 876b).

(c) An applicant is committed to a mental institution if he or she is formally committed to a mental institution by a court, board, commission, or other lawful authority, including involuntary commitment and commitment for lacking mental capacity, mental illness, and drug use. This does not include a commitment to a mental institution for observation or voluntary admission to a mental institution.

§§ 1572.111–1572.139 [Reserved]

§ 1572.141 Appeal procedures.

(a) *Scope.* This section applies to applicants who wish to appeal an Initial Determination of Threat Assessment.

(b) *Grounds for Appeal.* An applicant may appeal an Initial Determination of Threat Assessment if the applicant is asserting that he or she meets the security threat assessment standards identified in § 1572.5(c).

(c) *Appeal.* An applicant initiates an appeal by submitting a written reply to TSA or written request for materials from TSA. If the applicant fails to initiate an appeal within 30 days after receipt, the Initial Determination of Threat Assessment becomes final, and TSA serves a Final Determination of Threat Assessment on the State in which the applicant applied.

(1) *Request for materials.* Within 30 days after the date of service of the Initial Determination of Threat Assessment, the applicant may serve upon TSA a written request for copies of the materials upon which the Initial Determination was based.

(2) *TSA response.* (i) Within 30 days after receiving the applicant's request for materials, TSA serves copies of the releasable materials upon the applicant on which the Initial Determination was based. TSA will not include any classified information or other protected information described in paragraph (f) of this section.

(ii) Within 30 days after receiving the applicant's request for materials or written reply, TSA may request additional information or documents from the applicant that TSA believes are necessary to make a Final Determination.

(3) *Correction of records.* If the Initial Determination of Threat Assessment was based on a record that the applicant believes is erroneous, the applicant may correct the record, as follows:

(i) The applicant may contact the jurisdiction or entity responsible for the information and attempt to correct or complete information contained in his or her record.

(ii) The applicant must provide TSA with the revised record, or a certified true copy of the information from the appropriate entity, before TSA may determine that the applicant meets the standards for the security threat assessment.

(4) *Reply.* (i) The applicant may serve upon TSA a written reply to the Initial Determination of Threat Assessment within 30 days after service of the Initial Determination, or 30 days after the date of service of TSA's response to the applicant's request for materials under paragraph (d)(2) of this section, if the applicant served such request. The reply must include the rationale and information on which the applicant disputes TSA's Initial Determination.

(ii) In an applicant's reply, TSA will consider only material that is relevant to whether the applicant meets the standards described in paragraph (d) of this section for the security threat assessment in paragraph (b) of this section.

(5) *Final determination.* Within 30 days after TSA receives the applicant's reply, TSA serves a Final Determination of Threat Assessment or a Withdrawal of the Initial Determination as provided in paragraphs (d) or (e) of this section.

(d) *Final Determination of Threat Assessment.* (1) In the case of an appeal of an Initial Determination of Threat Assessment that is based on criminal offense under § 1572.103; immigration status under § 1572.105; or mental competency under § 1572.109; if the Director concludes that the applicant does not meet the security threat assessment standards described in § 1572.5, TSA serves a Final Determination of Threat Assessment upon the applicant and the issuing State.

(2) In the case of an appeal of an Initial Determination of Threat Assessment that is based on a threat to national security or transportation security, or of terrorism under § 1572.107, if the Assistant Secretary concludes that the applicant does not meet the security threat assessment standards described in § 1572.5, TSA serves a Final Determination of Threat Assessment upon the applicant and issuing State.

(3) The Final Determination includes a statement that the Director or Assistant Secretary has reviewed the Initial Determination, the applicant's reply and any accompanying information, if any, and any other materials or information available to him or her and has determined that the applicant poses a security threat warranting denial of an HME.

(e) *Withdrawal of Initial Determination.* If the Director or Assistant Secretary concludes that the applicant does not pose a security threat warranting denial of the HME, TSA serves a Withdrawal of the Initial Determination upon the applicant.

(f) *Nondisclosure of certain information.* In connection with the procedures under this section, TSA does not disclose classified information to the applicant, as defined in Executive Order 12968 section 1.1(d), and reserves the right not to disclose any other information or material not warranting disclosure or protected from disclosure under law.

(g) *Extension of time.* TSA may grant an applicant an extension of time of the limits described in this section for good cause shown. An applicant's request for an extension of time must be in writing and be received by TSA within a reasonable time before the due date to be extended. TSA may grant itself an extension of time for good cause.

(h) *Judicial review.* For purposes of judicial review, the Final Determination of Threat Assessment constitutes a final TSA order in accordance with 49 U.S.C. 46110.

(i) *Appeal of immediate revocation.* (1) If TSA directs a State to revoke an HME pursuant to § 1572.13(a) by issuing an Initial Determination of Threat Assessment and Immediate Revocation, the applicant may appeal this determination by following the appeal procedures described in paragraph (c) of this section.

§ 1572.143 Waiver procedures.

(a) *Scope.* This section applies to an applicant who—

(1) Has a disqualifying criminal offense described in § 1572.103(a)(5) through (a)(9), and paragraph 1572.103(a)(10) if the underlying criminal offense is in paragraphs 1572.103(a)(5) through (a)(9); or

(2) Has a disqualifying criminal offense described in § 1572.103(b); or

(3) Lacks mental capacity as described in § 1572.109.

(b) *Waivers.* (1) An applicant initiates a waiver request by sending a written request to TSA for a waiver at any time, but not later than 30 days after the date of service of the Final Determination of Threat Assessment.

(2) In determining whether to grant a waiver, TSA will consider the following factors:

(i) The circumstances of the disqualifying act or offense;

(ii) Restitution made by the applicant;

(iii) Any Federal or State mitigation remedies;

(iv) Court records or official medical release documents indicating that the individual no longer lacks mental capacity;

(v) Other factors that indicate the applicant does not pose a security threat warranting denial of the HME.

(c) *Grant or denial of waivers.* The Director will send a written decision granting or denying the waiver to the applicant and a Determination of No Security Threat to the State in which the applicant applied for the HME, within 30 days after service the applicant's request for a waiver, or longer period as TSA may determine for good cause.

(d) *Extension of time.* TSA may grant an applicant an extension of time of the limits described in paragraph (b) and (c) of this section for good cause shown. An applicant's request for an extension of time must be in writing and be received by TSA within a reasonable time before the due date to be extended. TSA may grant itself an extension of time for good cause.

Subpart C—Transportation of Explosives From Foreign Locations

§ 1572.201 Transportation of explosives from Canada to the United States via commercial motor vehicle.

(a) *Applicability.* This section applies to carriers that carry explosives from Canada to the United States using a driver who is not a United States citizen or lawful permanent resident alien of the United States.

(b) *Terms used in this section.* For purposes of this section:

Carrier means any ''motor carrier'' or ''motor private carrier'' as defined in 49 U.S.C. 13102(12) and (13), respectively.

Customs Service means the United States Customs Service.

Explosive means a material that has been examined by the Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, in accordance with 49 CFR 173.56, and determined to meet the definition for a Class 1 material in 49 CFR 173.50.

Known carrier means a person that has been determined by the Governments of Canada and the United States to be a legitimate business operating in accordance with all applicable laws and regulations governing the transportation of explosives.

Known driver means a driver of a motor vehicle who has been determined by the Governments of Canada and the United States to present no known security concern.

Known offeror means an offeror that has been determined by the Governments of Canada and the United States to be a legitimate business operating in accordance with all applicable laws and regulations governing the transportation of explosives.

Lawful permanent resident alien means a lawful permanent resident alien of the United States as defined by 8 U.S.C. 1101(a)(2).

Offeror means the person offering a shipment to the carrier for transportation from Canada to the United States, and may also be known as the ''consignor'' in Canada.

(c) *Prior approval of carrier, offeror, and driver.* (1) No carrier may transport in commerce any explosive into the United States from Canada via motor vehicle if the driver of the vehicle is a not a United States citizen or lawful permanent resident alien unless the carrier, offeror, and driver are identified on a TSA list as a known carrier, known offeror, and known driver, respectively.

(2) The carrier must ensure that it, its offeror, and its driver have been determined to be a known carrier, known offeror, and known driver, respectively. If any has not been so determined, the carrier must submit the following information to Transport Canada:

(i) The carrier must provide its:

(A) Official name;

(B) Business number;

(C) Any trade names; and

(D) Address.

(ii) The following information about any offeror of explosives whose shipments it will carry:

(A) Official name;

(B) Business number; and

(C) Address.

(iii) The following information about any driver the carrier may use to transport explosives into the United States from Canada who is neither a United States citizen nor lawful permanent resident alien of the United States:

(A) Full name;

(B) Canada Commercial Driver's License number; and

(C) Both current and most recent prior residential addresses.

(3) Transport Canada will determine that the carrier and offeror are legitimately doing business in Canada and will also determine that the drivers are properly licensed and present no known problems for purposes of this section. Transport Canada will notify TSA of these determinations by forwarding to TSA lists of known carriers, offerors, and drivers and their identifying information.

(4) TSA will update and maintain the list of known carriers, offerors, and drivers and forward the list to the Customs Service.

(5) Once included on the list, the carriers, offerors, and drivers need not obtain prior approval for future transport of explosives under this section.

(d) *TSA checks.* TSA may periodically check the data on the carriers, offerors and drivers to confirm their continued eligibility and may remove from the list any that TSA determines is not known or is a threat to security.

(e) *At the border—*

(1) *Driver who is not a United States citizen or lawful permanent resident alien.* Upon arrival at the border, and prior to entry into the United States, the driver must provide a valid Canadian commercial driver's license to the Customs Service.

(2) *Driver who is a United States citizen or lawful permanent resident alien.* If the Customs Service cannot verify that the driver is on the list, and if the driver is a United States citizen or lawful permanent resident alien, the

driver may be cleared by the Customs Service upon providing:

(i) A valid United States passport; or

(ii) One or more other document(s) including a form of United States Federal or state government-issued identification with photograph, acceptable to the Customs Service.

(3) *Compliance.* If a carrier attempts to enter the United States without having complied with this section, the Customs Service will deny entry of the explosives and may take other appropriate action.

§ 1572.203 Transportation of explosives from Canada to the United States via railroad carrier.

(a) *Applicability.* This section applies to railroad carriers that carry explosives from Canada to the United States using a train crew member who is not a United States citizen or lawful permanent resident alien of the United States.

(b) *Terms under this section.* For purposes of this section:

Customs Service means the United States Customs Service.

Explosive means a material that has been examined by the Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, in accordance with 49 CFR 173.56, and determined to meet the definition for a Class 1 material in 49 CFR 173.50.

Known railroad carrier means a person that has been determined by the Governments of Canada and the United States to be a legitimate business operating in accordance with all applicable laws and regulations governing the transportation of explosives.

Known offeror means an offeror that has been determined by the Governments of Canada and the United States to be a legitimate business operating in accordance with all applicable laws and regulations governing the transportation of explosives.

Known train crew member means an individual used to transport explosives from Canada to the United States who has been determined by the Governments of Canada and the United States to present no known security concern.

Lawful permanent resident alien means a lawful permanent resident alien of the United States as defined by 8 U.S.C. 1101(a)(2).

Offeror means the person offering a shipment to the railroad carrier for transportation from Canada to the United States, and may also be known as the ''consignor'' in Canada.

Railroad carrier means ''railroad carrier'' as defined in 49 U.S.C. 20102.

(c) *Prior approval of railroad carrier, offeror, and train crew member.* (1) No railroad carrier may transport in commerce any explosive into the United States from Canada via a train operated by a crew member who is not a United States citizen or lawful permanent resident alien unless the railroad carrier, offeror, and train crew member are identified on a TSA list as a known railroad carrier, known offeror, and known train crew member, respectively.

(2) The railroad carrier must ensure that it, its offeror, and each of its crew members have been determined to be a known railroad carrier, known offeror, and known train crew member, respectively. If any has not been so determined, the railroad carrier must submit the following information to Transport Canada:

(i) The railroad carrier must provide its:

(A) Official name;

(B) Business number;

(C) Any trade names; and

(D) Address.

(ii) The following information about any offeror of explosives whose shipments it will carry:

(A) Official name;

(B) Business number; and

(C) Address.

(iii) The following information about any train crew member the railroad carrier may use to transport explosives into the United States from Canada who is neither a United States citizen nor lawful permanent resident alien:

(A) Full name; and

(B) Both current and most recent prior residential addresses.

(3) Transport Canada will determine that the railroad carrier and offeror are legitimately doing business in Canada and will also determine that the train crew members present no known problems for purposes of this section. Transport Canada will notify TSA of these determinations by forwarding to TSA lists of known railroad carriers, offerors, and train crew members and their identifying information.

(4) TSA will update and maintain the list of known railroad carriers, offerors, and train crew members and forward the list to the Customs Service.

(5) Once included on the list, the railroad carriers, offerors, and train crew members need not obtain prior approval for future transport of explosives under this section.

(d) *TSA checks.* TSA may periodically check the data on the railroad carriers, offerors, and train crew members to confirm their continued eligibility and may remove from the list any that TSA determines is not known or is a threat to security.

(e) *At the border* (1) *Train crew members who are not United States citizens or lawful permanent resident aliens.* Upon arrival at a point designated by the Customs Service for inspection of trains crossing into the United States, the train crew members of a train transporting explosives must provide sufficient identification to the Customs Service to enable that agency to determine if each crew member is on the list of known train crew members maintained by TSA.

(2) *Train crew members who are United States citizens or lawful permanent resident aliens.* If the Customs Service cannot verify that the crew member is on the list and the crew member is a United States citizen or lawful permanent resident alien, the crew member may be cleared by the Customs Service upon providing:

(i) A valid United States passport; or

(ii) One or more other document(s) including a form of United States Federal or state government-issued identification with photograph, acceptable to the Customs Service.

(3) *Compliance.* If a carrier attempts to enter the United States without having complied with this section, the Customs Service will deny entry of the explosives and may take other appropriate action.

Issued in Arlington, Virginia on November 19, 2004.

David M. Stone,

Assistant Secretary.

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Federal Register

Wednesday,
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Part IX

The President

Proclamation 7847—National Farm-City Week, 2004

Federal Register
Vol. 69, No. 226
Wednesday, November 24, 2004

Presidential Documents

Title 3—

The President

Proclamation 7847 of November 19, 2004

National Farm-City Week, 2004

By the President of the United States of America

A Proclamation

America's farmers and ranchers provide a healthy, safe, and abundant food supply for our Nation and for people around the world. Their work depends on partnerships with shippers, processors, marketers, retailers, transporters, and many others, and their success is essential to America's prosperity. During National Farm-City Week, we recognize the importance of this cooperative network and the hard work and valuable contributions of those in our agricultural industry.

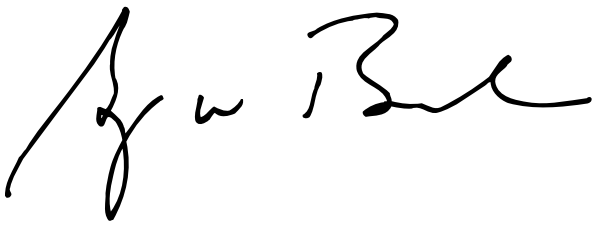
As one of our first industries, farming has long been vital to our Nation. Nearly half of the land in the United States is used for agricultural production, employing millions of workers, and providing consumers with food, clothing, and energy. In addition, America's farmers and ranchers are stewards of our land, using innovative conservation measures to protect our soil, water, and wildlife habitat.

Our cities also play a key role in our farm economy. Many of the industries that process, transport, and distribute agricultural goods are located in America's urban communities. Their work has contributed to record exports of farm products and to the prosperity of our Nation's agricultural industry.

My Administration will continue to work to strengthen American agriculture. As we observe National Farm-City Week, I join all our citizens in expressing gratitude to farmers, ranchers, and all those who work in our agricultural industry for their love of the land and love of our country.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim November 19 through November 25, 2004, as National Farm-City Week. I encourage all Americans to celebrate the cooperation between urban and rural communities and the extraordinary contributions of the agricultural industry to our Nation's vitality and prosperity.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of November, in the year of our Lord two thousand four, and of the Independence of the United States of America the two hundred and twenty-ninth.



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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''PLUS'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal_register/public_laws/public_laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 4381/P.L. 108–392

To designate the facility of the United States Postal Service located at 2811 Springdale Avenue in Springdale, Arkansas, as the ''Harvey and Bernice Jones Post Office Building''. (Oct. 30, 2004; 118 Stat. 2245)

H.R. 4471/P.L. 108–393

Homeownership Opportunities for Native Americans Act of 2004 (Oct. 30, 2004; 118 Stat. 2246)

H.R. 4481/P.L. 108–394

Wilson's Creek National Battlefield Boundary Adjustment Act of 2004 (Oct. 30, 2004; 118 Stat. 2247)

H.R. 4556/P.L. 108–395

To designate the facility of the United States Postal Service located at 1115 South Clinton Avenue in Dunn, North Carolina, as the ''General William Carey Lee Post Office Building''. (Oct. 30, 2004; 118 Stat. 2249)

H.R. 4579/P.L. 108–396

Truman Farm Home Expansion Act (Oct. 30, 2004; 118 Stat. 2250)

H.R. 4618/P.L. 108–397

To designate the facility of the United States Postal Service located at 10 West Prospect Street in Nanuet, New York, as the ''Anthony I. Lombardi Memorial Post Office Building''. (Oct. 30, 2004; 118 Stat. 2251)

H.R. 4632/P.L. 108–398

To designate the facility of the United States Postal Service located at 19504 Linden Boulevard in St. Albans, New York, as the ''Archie Spigner Post Office Building''. (Oct. 30, 2004; 118 Stat. 2252)

H.R. 4731/P.L. 108–399

To amend the Federal Water Pollution Control Act to reauthorize the National Estuary Program. (Oct. 30, 2004; 118 Stat. 2253)

H.R. 4827/P.L. 108–400

To amend the Colorado Canyons National Conservation Area and Black Ridge Canyons Wilderness Act of 2000 to rename the Colorado Canyons National Conservation Area as the McInnis Canyons National Conservation Area. (Oct. 30, 2004; 118 Stat. 2254)

H.R. 4917/P.L. 108–401

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H.R. 5027/P.L. 108–402

To designate the facility of the United States Postal Service located at 411 Midway Avenue in Mascotte, Florida, as the ''Specialist Eric Ramirez Post Office''. (Oct. 30, 2004; 118 Stat. 2257)

H.R. 5039/P.L. 108–403

To designate the facility of the United States Postal Service located at United States Route 1 in Ridgeway, North Carolina, as the ''Eva Holtzman Post Office''. (Oct. 30, 2004; 118 Stat. 2258)

H.R. 5051/P.L. 108–404

To designate the facility of the United States Postal Service located at 1001 Williams Street in Ignacio, Colorado, as the ''Leonard C. Burch Post Office Building''. (Oct. 30, 2004; 118 Stat. 2259)

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H.R. 5131/P.L. 108–406

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H.R. 5133/P.L. 108–407

To designate the facility of the United States Postal Service located at 11110 Sunset Hills Road in Reston, Virginia, as the ''Martha Pennino Post Office Building''. (Oct. 30, 2004; 118 Stat. 2297)

H.R. 5147/P.L. 108–408

To designate the facility of the United States Postal Service located at 23055 Sherman Way in West Hills, California, as the ''Evan Asa Ashcraft Post Office Building''. (Oct. 30, 2004; 118 Stat. 2298)

H.R. 5186/P.L. 108–409

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H.R. 5294/P.L. 108–410

John F. Kennedy Center Reauthorization Act of 2004 (Oct. 30, 2004; 118 Stat. 2303)

S. 129/P.L. 108–411

Federal Workforce Flexibility Act of 2004 (Oct. 30, 2004; 118 Stat. 2305)

S. 144/P.L. 108–412

To require the Secretary of Agriculture to establish a program to provide assistance to eligible weed management entities to control or eradicate noxious weeds on public and private land. (Oct. 30, 2004; 118 Stat. 2320)

S. 643/P.L. 108–413

Hibben Center Act (Oct. 30, 2004; 118 Stat. 2325)

S. 1194/P.L. 108–414

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