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3. The important elements of typical Federal Register documents.
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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: January 24, 2001, from 9:00 a.m. to Noon (E.S.T.)

WHERE: Office of the Federal Register
Conference Room
800 North Capitol Street, NW.
Washington, DC
(3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–CE–79–AD; Amendment 39–12066; AD 2000–26–16]

RIN 2120–AA64

Airworthiness Directives; Raytheon Aircraft Company Beech Models A36, B36TC, and 58 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Raytheon Aircraft Company (Raytheon) Beech Models A36, B36TC, and 58 airplanes. This AD requires you to inspect for missing rivets on the right hand side of the fuselage and, if necessary, install rivets. Raytheon has identified several instances of missing rivets on these airplanes. The actions specified by this AD are intended to install missing rivets in the right hand fuselage panel assembly in the area above the right wing and below the cabin door threshold. These rivets must be present for the fuselage to carry the ultimate load and prevent critical structural failure with loss of airplane control.

DATES: This AD becomes effective on February 16, 2001.

The Director of the **Federal Register** approved the incorporation by reference of certain publications listed in the regulations as of February 16, 2001.

ADDRESSES: You may get the service information referenced in this AD from Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140. You may examine this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–79–AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: T.N. Baktha, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4155; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Discussion

What Events Have Caused This AD?

Raytheon has identified several instances of missing rivets on these airplanes:

Model	Serial No.
Model A36 Bonanza	serials E–1 through E–3231; and E–3233.
Model B36TC Bonanza	serials EA–1 through EA–635.
Model 58 Baron	serials TH–1 through TH–1811; and TH–1813 through TH–1897.

Raytheon production and inspection personnel identified the missing rivets. The missing rivets are the result of a quality control problem.

What Are the Consequences if the Condition Is Not Corrected?

This condition results in the airplane being unable to carry the ultimate load with possible structural failure and loss of airplane control.

Has FAA Taken Any Action to This Point?

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Raytheon Beech Models A36, B36TC, and 58 airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on September 26, 2000 (65 FR 57751). The NPRM proposed to require you to inspect for missing rivets on the right hand fuselage and if necessary, install rivets.

Was the Public Invited To Comment?

Interested persons were afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

What Is FAA's Final Determination on This Issue?

After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. We determined that these minor corrections:

—Will not change the meaning of the AD; and

—Will not add any additional burden upon the public than was already proposed.

Cost Impact

How Many Airplanes Does This AD impact?

We estimate that this AD affects 3632 airplanes in the U.S. registry.

What Is the Cost Impact of This AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
1 workhour × $60 per hour = $60	No parts required for the inspection.	$60 per airplane	$60 × = $217,920.

We estimate the following costs to accomplish the modification if necessary:

Laobor cost	Parts cost	Total cost per airplane
4 workouts × $60 per hour = $240	$100 per airplane	$340 per airplane.

The manufacturer will allow warranty credit for labor and parts to the extent noted in the service bulletin.

Regulatory Impact

Does This AD Impact Various Entities?

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does This AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this action (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. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. FAA amends § 39.13 by adding a new AD to read as follows:

2000–26–16 Raytheon Aircraft Company: Amendment 39–12066; Docket No. 99–CE–79–AD.

(a) *What airplanes are affected by this AD?* This AD affects the following airplanes, certificated in any category:

Model	Serial No.
Model A36	E–1 through E–3231, and E–3233.
Model B36TC	EA–1 through EA–635.
Model 58	TH–1 through TH–1811, and TH-1813 through TH–1897.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to install missing rivets in the right hand fuselage panel assembly in the area above the right wing and below the cabin door threshold. These rivets must be present for the fuselage to carry the ultimate load and prevent critical structural failure with loss of control of the airplane.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must do the following actions:

Actions	Compliance times	Procedures
(1) Inspect for up to 9 missing rivets between fuselage station (F.S.) 83.00 and F.S. 91.00 at water line (W.L.) 90.3.	Inspect within the next 100 hours time-in-service after February 16, 2001 (the effective date of this AD).	Do this inspection in accordance with the ACCOMPLISHMENT INSTRUCTIONS paragraph of Raytheon Mandatory Service Bulletin SB 53–3341, Revision 1, Revised: May 2000, and the Bonanza Series Maintenance Manual or Baron Model 58 Series Maintenance Manual.
(2) If you find rivets are missing, install these rivets.	Before further flight after the inspection	Do these actions in accordance with the ACCOMPLISHMENT INSTRUCTIONS paragraph of Raytheon Mandatory Service Bulletin SB 53–3341, Revision 1, Revised: May 2000, and the Bonanza Series Maintenance Manual or Baron Model 58 Series Maintenance Manual.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact T.N. Baktha, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4155; facsimile: (316) 946–4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Raytheon Mandatory Service Bulletin SB 53–3341, Revision 1, revised May 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on February 16, 2001.

Issued in Kansas City, Missouri, on December 22, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–183 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–CE–55–AD; Amendment 39–12067; AD 2000–26–17]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Models PC–12 and PC–12/45 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to Pilatus Aircraft Ltd. (Pilatus) Models PC–12 and PC–12/45 airplanes that are equipped with a certain windshield configuration. This AD requires you to incorporate pilot's operating handbook (POH) information that prohibits the operation of the windshield heating system in the ''LIGHT'' mode, and requires you to modify the windshield deicing system wiring and circuit breakers. You can remove the POH information after accomplishing the modification. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland. The actions specified by this AD are intended to prevent loss of electrical power to the windshield deicing system due to operation in the ''LIGHT'' mode, which could result in icing of the windshield and loss of control of the airplane.

DATES: This AD becomes effective on February 24, 2001.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of February 24, 2001.

ADDRESSES: You may get the service information referenced in this AD from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 619 6224; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021; telephone: (303) 465–9099; facsimile: (303) 465–6040. You may examine this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–CE–55–AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4141; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What Events Have Caused This AD?

The Federal Office for Civil Aviation (FOCA), which is the airworthiness authority for Switzerland, recently notified the FAA that an unsafe condition may exist on certain Pilatus Models PC–12 and PC–12/45 airplanes. The FOCA reports that the electrical load of the left hand (LH) and right hand (RH) windshields can become too high during flight at cruise altitudes when the ''LIGHT'' mode is selected on the windshield deicing system. The FOCA references eight instances where prolonged operation of the windshield deicing system in the ''LIGHT'' mode caused this system to temporarily shut down.

The airplanes involved in the above instances were equipped with part number (P/N) 959.81.10.107 LH and P/N/ 959.81.10.108 RH windshields.

What Are the Consequences if the Condition Is Not Corrected?

Operation of the existing design windshield deicing system in the ''LIGHT'' position can overload the electrical capacity of the wiring and circuit breakers. This could result in complete electrical power loss to the windshield and icing of the windshield.

Has FAA Taken Any Action to this Point?

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to Pilatus Models PC–12 and PC–12/45 airplanes that are equipped with a certain windshield configuration. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on October 2, 2000 (65 FR 58675). The NPRM proposed to require you to incorporate POH information that would prohibit the operation of the windshield heating system in the ''LIGHT'' mode, and would require you to modify the windshield deicing system wiring and circuit breakers. You could remove the POH information after accomplishing the modification.

Was the Public Invited To Comment?

Interested persons were afforded an opportunity to participate in the making of this amendment. No comments were

received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

What Is FAA's Final Determination on This Issue?

After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. We determined that these minor corrections:

—Will not change the meaning of the AD; and

—Will not add any additional burden upon the public than was already proposed.

Cost Impact

How Many Airplanes Does This AD Impact?

We estimate that this AD affects 108 airplanes in the U.S. registry.

What Is the Cost Impact of This AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
18 workhours×$60 per hour $1,080	Pilatus will provide free-of-charge.	$1,080 per airplane	$116,640.

Compliance Time of This AD

What Is the Compliance Time of This AD?

The compliance time of this AD is as follows:

—Incorporation of the POH temporary revision: ''Within the next 30 days after the effective date of this AD;'' and

—Modification: ''Within the next 12 months after the effective date of this AD.''

Why Is the Compliance of This AD in Calendar Time Instead of Hours Time-in-Service (TIS)?

Although loss of electrical power to the windshield deicing system due to operation in the ''LIGHT'' mode is unsafe during flight, the condition is not a direct result of airplane operation. The chance of this situation occurring is the same for an airplane with 10 hours time-in-service (TIS) as it would be for an airplane with 500 hours TIS. A calendar time for compliance will assure that the unsafe condition is addressed on all airplanes in a reasonable time period.

Regulatory Impact

Does This AD Impact Various Entities?

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does This AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this action (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. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. FAA amends § 39.13 by adding a new AD to read as follows:

2000–26–17 Pilatus Aircraft Ltd.: Amendment 39–12067; Docket No. 2000–CE—55AD.

(a) *What airplanes are affected by this AD?* This AD affects Models PC–12 and PC–12/45 airplanes, manufacturer serial number (MSN) 101 through MSN 320, that are:

(1) certificated in any category; and

(2) equipped with part number (P/N) 959.81.10.107 LH and P/N 959.81.10.108 RH windshields (PPG P/N NP172121–5 LH and NP172121–6 RH or FAA-approved equivalent part numbers).

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent loss of electrical power to the windshield deicing system due to operation in the ''LIGHT'' mode, which could result in icing of the windshield and loss of control of the airplane.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Action	Compliance Time	Procedures
(1) Insert Temporary Revision No. 21 to PC–12 Pilot's Operating Handbook, Report No. 01973–001, Section 2, Windshield Heater Operation 101–320, Issued: May 19, 2000..	Within the next 30 days after February 24, 2001 (the effective date of this AD), unless already accomplished..	Anyone who holds at least a private pilot certificate, as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7), may incorporate the pilot's operating handbook (POH) revision required by this AD. You must make an entry into the aircraft records that shows compliance with this AD, in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

Action	Compliance Time	Procedures
(2) Modify the windshield deicing system wires and circuit breakers. You may remove the POH temporary revision referenced in paragraph (d)(1) of this AD after accomplishing this modification..	Within the next 12 months after February 24, 2001 (the effective date of this AD), unless already accomplished..	In accordance with the modification procedures in the Accomplishment Instructions section of Pilatus Service Bulletin No. 30–006, dated May 22, 2000.
(3) Do not install, on any affected airplane, P/N 959.81.10.107 LH and P/N 959.81.10.108 RH windshields (PPG P/N NP172121–5 LH and NP172121–6 RH or FAA-approved equivalent part numbers), without incorporating the modification required in paragraph (d)(2) of this AD..	As of February 24, 2001 (the effective date of this AD.).	Not applicable.

Note 1: Temporary Revision No. 21 to PC–12 Pilot's Operating Handbook, Report No. 01973–001, Section 2, Windshield Heater Operation 101–320, Issued: May 19, 2000, eliminates the need for Temporary Revision No. 14 in the POH.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 329–4141; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Pilatus Service Bulletin No. 30–006, dated May 22, 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective ?* This amendment becomes effective on February 24, 2001.

Note 3: The subject of this AD is addressed in Swiss AD HB 2000–393, dated September 6, 2000.

Issued in Kansas City, Missouri, on December 22, 2000.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–184 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. 00N–1634]

Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its administrative regulations governing the public disclosure of written information for consideration by an advisory committee at an advisory committee meeting. This action amends the regulations to state that the written information for consideration by an advisory committee at a committee meeting is available for public disclosure, whenever practicable, before or at the time of the meeting. FDA is taking this action to reflect current FDA policy in conformance with applicable law. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

DATES: This rule is effective May 23, 2001. Submit written comments by March 26, 2001. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before April 23, 2001, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation notice in the **Federal Register**. If timely significant adverse comments are received, the agency will publish a document of significant adverse comments in the **Federal Register** and withdraw this direct final rule before April 23, 2001.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Discussion

A. Background

Advisory committees provide independent advice and recommendations to FDA on scientific and technical matters related to products regulated by the agency. To assist committee members in preparing to discuss the issues that will be raised at a committee meeting, the agency and, in certain circumstances, affected members of the regulated industry prepare written background materials

for committee members. Generally, advisory committee members are provided these materials soon after they are completed, often weeks before a committee meeting.

FDA's advisory committees are established under the Federal Advisory Committee Act (5 U.S.C. app. 2) (the FACA). FDA's procedures for the administration of advisory committees are set forth in part 14 (21 CFR part 14). Section 14.75(a)(1) states that, unless it is otherwise exempt from disclosure, written information for consideration by the committee at the meeting should be available for public disclosure at the same time it is made available to the committee. As described below, FDA finds this provision for simultaneous disclosure unnecessary and detrimental to the advisory committee process. Therefore, FDA is amending this provision in its administrative regulations.

B. Rationale for the Rule

As interpreted by case law, the FACA requires that, whenever practicable and subject to any applicable exemption of the Freedom of Information Act (the FOIA) (5 U.S.C. 552), information prepared for or provided to an advisory committee be made publicly available before or at the time of the advisory committee meeting at which the information is used and discussed (see, e.g., *Food Chemical News* v. *Department of Health and Human Services*, 980 F.2d 1468 (D.C. Cir. 1992)). Therefore, FDA's provision for disclosing information to the public at the same time the information is provided to the advisory committee (§ 14.75(a)(1)) goes beyond the requirements of the FACA. The agency is not obligated under the FACA to provide the materials to the public at the same time they are provided to the advisory committee.

Under § 14.75(b)(1), the public disclosure provision of § 14.75(a)(1) is subject to FDA's regulations in part 20 (21 CFR part 20). The regulations in part 20 describe the agency's policies and procedures for disclosing information to the public under the FOIA. Information that generally may be released to the public, including information described in § 14.75(a)(1), may not be released if it falls within one or more of the exemptions described in part 20. Written materials provided to an advisory committee for consideration at a committee meeting often include information that is not made publicly available because the information is subject to one or more of the following exemptions: (1) Trade secrets and commercial or financial information that is privileged or confidential (§ 20.61); (2) inter- or intra-agency memoranda or letters (§ 20.62); and (3) personnel, medical, and similar files, the disclosure of which constitutes a clearly unwarranted invasion of personal privacy (§ 20.63).

If written materials contain some information that is disclosable and some information that is not subject to disclosure, the agency can make the materials available to the public after deleting the nondisclosable information (§ 20.22). The process of reviewing the advisory committee materials, determining which information is exempt from disclosure, and redacting the documents to remove the nondisclosable information requires a significant amount of time. For example, in the **Federal Register** of December 22, 1999 (64 FR 71794), FDA announced the availability of a draft guidance document entitled ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000.'' In the draft guidance document, the agency described a 4-week process of reviewing and redacting an advisory committee package submitted by a sponsor of a new drug application and a 3-week process of reviewing and redacting an advisory committee package generated by the Center for Drug Evaluation and Research.

Materials that are otherwise exempt from disclosure under §§ 20.61, 20.62, and 20.63, however, may be disclosed to advisory committee members who are special government employees for use in connection with their work on an advisory committee (§ 20.84). Therefore, the materials provided to advisory committee members need not go through the extensive and time-consuming review and redaction process.

Advisory committees provide meaningful advice to FDA on technical and scientific matters related to the development and evaluation of FDA-regulated products. The value of the advice provided by FDA advisory committees depends, in large part, on the ability of advisory committee members to evaluate diverse, complex, and sometimes contentious scientific issues during the course of a committee meeting. It is crucial that the agency provide advisory committee members background information as soon as practicable after the materials are generated so the members can adequately prepare for the meeting. Because § 14.75(a)(1) provides for the public availability of these materials at the same time as the materials are provided to an advisory committee, and because the advisory committee materials often need to be redacted before being made publicly available, complying with § 14.75(a)(1) would require the agency to wait until the materials are redacted before sending the information to the advisory committees. This, in turn, would result in less time for the committee members to review the materials prior to the committee meeting. This delay would be detrimental to the advisory committee process. Furthermore, simultaneous availability of briefing materials to the advisory committee and to the public is not required under the FACA.

Therefore, the agency is amending § 14.75(a)(1) to state that the written information for consideration by an advisory committee at any meeting is available for public disclosure whenever practicable, before or at the time of the meeting.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule revises § 14.75(a)(1) to reflect current agency policy in conformance with applicable law. The actions taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comment on this rule.

If FDA does not receive significant adverse comment by March 26, 2001, the agency will publish a document in the **Federal Register** before April 23, 2001, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change. 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 before April 23, 2001.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, identical to the direct final rule, that provides a procedural framework within which the

rule may be finalized in the event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed 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 and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to part of this rule and that part may be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

IV. Analysis of Impacts

FDA has examined the impacts of this direct final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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 rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in the other two statutes. This rule is not a significant regulatory action as defined by the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. The agency has considered the effect that this rule will have on small entities. Because the rule amends only internal agency procedures, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). FDA is not required to prepare a statement of the costs and benefits of this rule because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final 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 final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

This direct final rule does not require information collections and, thus, is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

VII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this rule by March 26, 2001. Two copies of any 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended to read as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 is revised to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 14.75 is amended by revising paragraph (a)(1) to read as follows:

§ 14.75 Examination of administrative record and other advisory committee records.

(a) * * *

(1) The written information for consideration by the committee at any meeting: Whenever practicable, before or at the time of the meeting.

* * * * *

Dated: December 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–389 Filed 1–5–01; 8:45 am]

BILLING CODE 4160–01–F

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Chapter VIII

[CSOSA–0001]

RIN 3225–ZA00

Organization and Functions

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Final rule.

SUMMARY: The Court Services and Offender Supervision Agency for the District of Columbia (''CSOSA'') is issuing regulations describing its organization and general functions. This description includes information on the District of Columbia Pretrial Services Agency (''PSA''), an independent entity within CSOSA. CSOSA provides supervisory and treatment services to individuals on probation, parole and supervised release for District of Columbia Code violations. CSOSA also

provides supervisory and treatment services to offenders from other jurisdictions in accordance with the Interstate Parole and Probation Compact. PSA supervises, monitors and provides treatment services to defendants in the U.S. District Court and the United States Court of Appeals for the District of Columbia Circuit and to individuals on pretrial release for District of Columbia Code violations.

EFFECTIVE DATE: January 8, 2001.

ADDRESSES: Office of General Counsel, CSOSA, Room 1253, 633 Indiana Avenue, NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Records Manager; telephone (202) 220–5359; e-mail roy.nanovic@csosa.gov.

SUPPLEMENTARY INFORMATION: The Court Services and Offender Supervision Agency for the District of Columbia (''CSOSA'') was established within the Executive Branch of the Federal Government by the National Capital Revitalization and Self-Government Improvement Act of 1997 (''Revitalization Act''), Pub. L. 105–33, 111 Stat. 251, 712 (D.C. Code 24–1232, 24–1233). On August 4, 2000, CSOSA was certified by the Attorney General as an independent Federal agency.

The Revitalization Act requires CSOSA to provide supervision, through qualified supervision officers, to offenders on probation, parole, and supervised release for violation of District of Columbia Code offenses. Accordingly, CSOSA supervises all offenders placed on probation by the Superior Court of the District of Columbia, and all individuals on parole pursuant to the District of Columbia Code. CSOSA provides supervision to offenders from other jurisdictions in accordance with the provisions of the Interstate Parole and Probation Compact. In accordance with its supervisory functions and as authorized by the Sex Offender Registration Act of 1999 (DC Law 13–137, D.C. Code 24–1101 et seq.), CSOSA operates and maintains the sex offender registry for the District of Columbia.

The DC Pretrial Services Agency (''PSA''), an independent entity within CSOSA, assists the trial and appellate levels of both the federal and local courts in determining eligibility for pretrial release by providing verified background information and criminal histories on all arrestees and recommendations about available release options. PSA is further responsible for supervising defendants released from custody during the pretrial period by monitoring compliance with conditions of release and by ensuring that they appear for scheduled court hearings. PSA also provides defendants with the opportunity to participate in a variety of social intervention programs that decrease the likelihood of future criminal behavior.

CSOSA's mission is to increase public safety, prevent crime, reduce recidivism, and support the fair administration of justice in close collaboration with the community. Law enforcement agencies, the courts, corrections, and parole authorities each play critical roles in addressing crime and ensuring public safety. CSOSA, together with PSA, coordinates closely with these entities to fulfill its role in the criminal justice process by providing supervisory and treatment services to individuals on pretrial release, probation, parole and supervised release, and by assisting federal and local courts in determining eligibility for release.

CSOSA's regulations are being codified in Chapter VIII of Title 28 of the Code of Federal Regulations. Part 800 consists of a general statement of organization and functions, including addresses for CSOSA's and PSA's central and field offices, and addresses for submitting Freedom of Information Act/Privacy Act requests, legal process, and tort claims. A more detailed statement of organization and functions will appear in the ''United States Government Manual.''

Matters of Regulatory Procedure

Administrative Procedure Act

Because this rule pertains to agency organization, CSOSA is issuing the rule as final without general notice of proposed rulemaking and without any delay in its effectiveness. Any interested person, however, who wishes to submit comments on the rule may do so by writing or e-mailing the agency at the addresses given above in the ''Addresses'' and ''For Further Information Contact'' captions.

Executive Order 12866

This rule falls within a category of actions that the Office of Management and Budget (OMB) has determined not to constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866 and, accordingly, CSOSA did not formally submit it to OMB for review.

Executive Order 13132

This rule will not 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. Therefore, in accordance with Executive Order 13132, the Director of CSOSA has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of CSOSA, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule and by approving it certifies that this rule will not have a significant economic impact upon a substantial number of small entities. This rule pertains to agency management, and its economic impact is limited to the agency's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, the Director of CSOSA has determined that no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

We want to make CSOSA's documents easy to read and understand. If you have suggestions on how to improve the clarity of these regulations, write, e-mail, or call CSOSA's Records Manager (Roy Nanovic), at the address or telephone number given above in the ''Addresses'' and ''For Further Information Contact'' captions.

List of Subjects in 28 CFR Part 800

Organization and Functions (Government Agencies); Probation and Parole.

Jasper Ormond,
Interim Director.

Accordingly, we amend Title 28 of the Code of Federal Regulations by adding a new chapter VIII, consisting of Part 800 to read as follows:

Chapter VIII—Court Services and Offender Supervision Agency for the District of Columbia

PART 800—ORGANIZATION AND FUNCTIONS

Sec.
800.1 Statutory authorization.
800.2 Mission.
800.3 Functions and responsibilities.
800.4 Director.
800.5 Agency components.
Appendix A.

Authority: 5 U.S.C. 301; Pub. L. 105–33, 111 Stat. 251, 712 (D.C. Code 24–1232, 24–1233).

§ 800.1 Statutory authorization.

The National Capital Revitalization and Self-Government Improvement Act of 1997 (''Revitalization Act'') established the Court Services and Offender Supervision Agency for the District of Columbia (''CSOSA'') within the federal government as an independent executive branch agency and placed the District of Columbia Pretrial Services Agency as an independent entity within CSOSA. In addition, the District of Columbia Public Defender Service, an independent District of Columbia agency, receives its appropriated federal funds through a transfer from CSOSA.

§ 800.2 Mission.

CSOSA's mission is to increase public safety, prevent crime, reduce recidivism, and support the fair administration of justice in close collaboration with the community.

§ 800.3 Functions and responsibilities.

(a) *Community Supervision Services.* (1) The Revitalization Act requires CSOSA to provide supervision, through qualified supervision officers, to offenders on probation, parole, and supervised release for violation of District of Columbia Code offenses. The Agency carries out its responsibilities on behalf of the court or agency having jurisdiction over the person being supervised. Accordingly, CSOSA supervises all offenders placed on probation by the Superior Court of the District of Columbia, and all individuals on parole pursuant to the District of Columbia Code. CSOSA supervises offenders from other jurisdictions in accordance with the provisions of the Interstate Parole and Probation Compact.

(2) CSOSA is also required to determine uniform supervision and reporting practices, develop and operate intermediate sanctions programs for sentenced offenders, and arrange for the supervision of District of Columbia Code offenders in jurisdictions outside the District of Columbia.

(3) In accordance with its supervisory functions and as authorized by the Sex Offender Registration Act of 1999 (D.C. Law 13–137, D.C. Code 24–1101 *et seq.*), CSOSA operates and maintains the sex offender registry for the District of Columbia.

(b) *Pretrial Services.* (1) The District of Columbia Pretrial Services Agency (''PSA'') assists the trial and appellate levels of both the federal and local courts in determining eligibility for pretrial release by providing verified background information and criminal histories on all arrestees and recommendations about available release options.

(2) PSA is further responsible for supervising defendants released from custody during the pretrial period by monitoring compliance with conditions of release and by ensuring that they appear for scheduled court hearings.

(3) PSA also provides defendants with the opportunity to participate in a variety of social intervention programs that decrease the likelihood of future criminal behavior.

§ 800.4 Director.

(a) CSOSA is headed by a Director appointed by the President, by and with the advice and consent of the Senate, for a term of six years.

(b) PSA is headed by a Director appointed by the Chief Judge of the United States Court of Appeals for the District of Columbia Circuit and the Chief Judge of the United States District Court for the District of Columbia in consultation with an Executive Committee. The Executive Committee includes the four chief judges of the local and Federal trial and appellate courts, the United States Attorney for the District of Columbia, the Director of the District of Columbia Public Defender Service, and the Director of CSOSA.

§ 800.5 Agency components.

(a) *CSOSA.*

(1) Office of the Director (including the Deputy Director).

(2) Office of the General Counsel.

(3) Community Supervision Services.

(4) Office of Community Justice Programs.

(5) Special Criminal Justice Projects.

(6) Office of Planning and Evaluation.

(7) Office of Professional Responsibility.

(8) Equal Employment Opportunity, Diversity, and Special Programs.

(9) Office of Legislative, Intergovernmental, and Public Affairs.

(10) Information Technology Services.

(11) Office of Management and Administration.

(12) Office of Human Resources.

(b) *PSA.*

(1) Office of the Director (including the Deputy Director).

(2) Planning, Analysis and Evaluation.

(3) Community Justice Programs.

(4) Office of Operations (including Information Technology and Forensic Toxicology and Drug Testing Laboratory).

(5) Human Resources Management.

(6) Finance and Administration.

Appendix A to Part 800—Agency Addresses

I. Central Offices

Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue, NW., Washington, DC 20004

CSOSA Community Supervision Services, 300 Indiana Avenue, NW., Washington, DC 20001

District of Columbia Pretrial Services Agency, 633 Indiana Avenue, NW., Washington, DC 20004

II. Field Offices

Court Services and Offender Supervision Agency for the District of Columbia/ Community Supervision Services

CSS Field Office, 409 E. Street, NW., Washington, DC 20001

CSS Field Office, 401 New York Avenue, NE., Washington, DC 20002

CSS Field Office, 1707 Kalorama Road, NW., Washington, DC 20009

CSS Field Office, 1418 Good Hope Road, SE., Washington, DC 20020

CSS Field Office, 3850 S. Capitol Street, SE., Washington, DC 20032

CSS Field Office, 1230 Taylor Street, NW., Washington, DC 20011

District of Columbia Pretrial Services Agency

Office of Operations Branch, 300 Indiana Avenue, NW., Washington, DC 20001

Office of Operations Branch, 500 Indiana Avenue, NW., Washington, DC 20001

Office of Operations Branch, 333 Constitution Avenue, NW., Washington, DC 20001

Office of Operations Branch, 601 Indiana Avenue, NW., Washington, DC 20004

IV. FOIA/PA Requests (CSOSA and PSA)

Office of the General Counsel (FOIA), Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue, NW., Washington, DC 20004

IV. Service of Process (CSOSA and PSA, except for PSA subpoenas)

Office of the General Counsel, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue, NW., Washington, DC 20004

V. Tort Claims (CSOSA and PSA)

Office of the General Counsel, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue, NW., Washington, DC 20004

[FR Doc. 01–395 Filed 1–5–01; 8:45 am]

BILLING CODE 3129–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–00–029]

RIN 2115–AE47

Drawbridge Operating Regulation; Mississippi River, Iowa and Illinois

AGENCY: Coast Guard, DOT.

ACTION: Temporary deviation.

SUMMARY: The Commander, Eighth Coast Guard District, has authorized a deviation from the regulation governing the Burlington Railroad Drawbridge, Mile 403.1, Upper Mississippi River at Burlington, Iowa. This deviation allows the drawbridge to remain closed-to-navigation for 60 days from 12:01 a.m., December 31, 2000, until 12:01 a.m., March 1, 2001. The drawbridge will open on signal if at least six (6) hours advance notice is given.

DATES: This temporary deviation is effective from 12:01 a.m., December 31, 2000, until 12:01 a.m., March 1, 2001.

FOR FUTHER INFORMATION CONTACT: Roger K. Wiebusch, Bridge Administrator, Commander (obr), Eighth Coast Guard District, 1222 Spruce Street, St. Louis, MO 63103–2832, (314) 539–3900, extension 378.

SUPPLEMENTARY INFORMATION: The Burlington Railroad Drawbridge provides a vertical clearance of 21.5 feet above normal pool in the closed to navigation position. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This deviation has been coordinated with waterway users who do not object.

This deviation allows the bridge to remain closed-to-navigation from 12:01 a.m., December 31, 2000, to 12:01 a.m., March 1, 2001, with openings provided upon receipt of six (6) hours advance notice. Advance notice may be given by calling Mr. Al Poole, (309) 345–6103 during work hours and Mr. Larry Moll, (309) 752–5244, after hours. The drawbridge normally opens on signal.

Dated: December 28, 2000

K.J. Eldridge,

Captain, U.S. Coast Guard, Acting Commander, Eighth Coast Guard District.

[FR Doc. 01–436 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF EDUCATION

34 CFR Part 606

Developing Hispanic-Serving Institutions Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Final regulations.

SUMMARY: When we published final regulations for the Developing Hispanic-Serving Institutions (HSI) Program in the **Federal Register** of December 15, 1999, it appears that one of the regulatory provisions, dealing with the eligibility of branch campuses to receive grants, could be viewed in a manner that would result in an unintended change of policy. To rectify this problem, we are revising that regulation to more clearly reflect our long standing policy that a branch campus is eligible to apply for an HSI grant if the branch campus serves the appropriate number of Hispanic students even if the main campus does not.

DATES: These regulations are effective February 7, 2001.

FOR FURTHER INFORMATION CONTACT: Sophia McArdle, U.S. Departmnet of Education, 1990 K Street, NW., Room 6061, Washington, DC 20006–8512. Telephone: (202) 219–7078. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT.**

SUPPLEMENTARY INFORMATION:

Background

The Higher Education Amendments of 1992, Pub. Law 102–325, amended the Higher Education Act of 1965, as amended (HEA), by adding the Developing Hispanic Serving-Institutions (HSI) Program as an authorized program under Title III, Part A of the HEA. The HSI Program was authorized in section 316 of Title III of the HEA.

Under section 316, in general, an HSI institution was an institution that satisfied the statutory definition of an ''eligible institution'' contained in section 312 of the HEA, and had at least 25 percent of its enrollment consist of Hispanic students. An eligible institution under section 312 of the HEA basically satisfied four conditions. Two of the conditions related to accreditation and licensure. The other two required the institution to have a high percentage of low income students and low education and general (E&G) expenditures.

Under section 312, a branch campus of an eligible institution also qualified as an eligible institution if its main campus satisfied all four conditions and it, on its own, satisfied the last two.

Regulations that we promulgated to implement these institutional eligibility requirements were codified in 34 CFR 607.2(b) and (d). The regulations did not specifically address whether the main campus of a branch campus that applied for an HSI Program grant had to satisfy the Hispanic student enrollment requirement. However, it was the Department's policy that a main campus did not have to qualify as an eligible HSI institution in terms of student enrollment if the branch campus is qualified.

In the Higher Education Amendments of 1998, Public Law 105–244, the Congress moved the HSI Program into Title V of the HEA and reenacted, in that title, all the relevant provisions that governed that program while it was part of Title III of the HEA. To accommodate that statutory change, we codified all the HSI Program requirements in a new part, 34 CFR Part 606. The recodification was technical in nature and did not involve any change in policy. Therefore, when we published Part 606 in the **Federal Register** on December 15, 1999, we waived rulemaking. However, it has recently come to our attention that one of the recodified regulatory provisions has been read by some as though it, in fact, made a change in policy. That provision was § 606.2(b), relating to the eligibility of a branch campus to qualify as an eligible HSI institution.

As presently written, it could be viewed that in order for a branch campus to qualify as an eligible HSI institution, it and its main campus must have an enrollment of at least 25 percent Hispanic students. As described above, however, such a reading would be inconsistent with the Department's policy that the main campus does not have to satisfy that requirement along

with the branch campus. Therefore, we are revising § 602.2(b) to more clearly reflect the Department's long-standing policy.

Waiver of Proposed Rulemaking

Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed regulations. However, these regulations merely clarify statutory changes and do not establish or effect substantive policy. Therefore, under 5 U.S.C. 553(b)(8), the Secretary has determined that proposed regulations are unnecessary and contrary to public interest.

Regulatory Flexibility Act Certification

The Secretary certifies that these regulations would not have a significant economic impact on a substantial number of small entities.

The small entities that would be affected by these regulations are small institutions of higher education (IHEs) receiving Federal funds under this program. However, the regulations would not have a significant economic impact on the small IHEs affected because the regulations would not impose excessive regulatory burdens or require unnecessary Federal supervision. The regulations would impose minimal requirements to ensure the proper expenditure of program funds.

Paperwork Reduction Act of 1995

These final regulations do not contain any information collection requirements.

Electronic Access to this Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news.html

To use PDF, you must have Adobe Acrobat Reader which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at:

http://www.access.gpo.gov/nara/index.html

(Catalog of Federal Domestic Assistance Numbers: 84.031S, 84.031A, and 84.031B)

List of Subjects in 34 CFR Part 606

Colleges and universities, Grant programs-education, Reporting and recordkeeping requirements.

Dated: December 29, 2000.

A. Lee Fritschler

Assistant Secretary, Office of Postsecondary Education.

For the reasons discussed in the preamble, the Secretary amends Title 34 of the Code of Federal Regulations by amending part 606 as follows:

PART 606—DEVELOPING HISPANIC-SERVING INSTITUTIONS PROGRAM

1. The authority citation for part 606 continues to read as follows:

Authority: 20 U.S.C. 1101 *et seq.*, unless otherwise noted.

2. Section 606.2 is amended by revising paragraph (b) to read as follows:

§ 606.2 What institutions are eligible to receive a grant under the Developing Hispanic-Serving Institutions Program?

* * * * *

(b) A branch campus of a Hispanic-Serving institution is eligible to receive a grant under this part if—

(1) The institution as a whole meets the requirements of paragraphs (a)(3) through (a)(6) of this section; and (2)

The branch campus satisfies the requirements of paragraphs (a)(1) through (a)(4) of this section.

* * * * *

[FR Doc. 01–430 Filed 1–5–01; 8:45 am]

BILLING CODE 4000–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6928–2]

RIN 2060–AH96

National Emission Standards for Hazardous Air Pollutants from Off-Site Waste and Recovery Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical corrections and amendments.

SUMMARY: Under the Clean Air Act (CAA), the EPA promulgated the National Emission Standards for Hazardous Air Pollutants (NESHAP) from Off-Site Waste and Recovery Operations (OSWRO) on July 1, 1996 with subsequent amendments on July 20, 1999. The promulgated rule requires new and existing major sources to control emissions of hazardous air pollutants (HAP) to the level reflecting application of the maximum achievable control technology. The technical corrections and minor technical amendments in this action will not change the basic control requirements of the rule or the level of health protection it provides.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because the changes to the rule are minor technical corrections, are noncontroversial in nature, and do not substantively change the requirements of the OSWRO rule. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

Section 553(d)(3) allows an agency, upon finding good cause, to make a rule effective immediately. Because today's changes do not substantively change the requirements of the OSWRO rule, we find good cause to make these amendments effectively immediately.

EFFECTIVE DATE: January 8, 2001.

ADDRESSES: Docket No. A–92–16 contains the supporting information for the original OSWRO NESHAP and this action. The docket is located at the U.S. EPA in room M–1500, Waterside Mall (ground floor), 401 M Street SW, Washington, DC 20460, and may be inspected from 8:00 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Ms. Elaine Manning, Waste and Chemical Processes Group, Emission Standards Division (MD–13), U.S. EPA, Research Triangle Park, NC, 27711, telephone number (919) 541–5499, facsimile number (919) 541–0246, electronic mail address manning.elaine@epa.gov.

SUPPLEMENTARY INFORMATION: *Regulated Entities.* Entities potentially regulated by this action include the following types of facilities if the facility receives ''off-site material'' as defined in the rule, and the facility is determined to be a major source of emissions of HAP as defined in 40 CFR 63.2.

Category	Examples of regulated entities
Industry	Businesses that receive waste, used oil, or used solvent from off-site locations and manage this material in any of the following waste management or recovery operations: hazardous waste treatment, storage, and disposal facilities (TSDF); hazardous wastewater treatment operations exempted from air emission control requirements in 40 CFR parts 264 or 265; nonhazardous wastewater treatment facilities other than publicly owned treatment works; used solvent recovery operations; recovery operations that recycle or reprocess hazardous waste and are exempted from regulation as a TSDF in 40 CFR parts 264 or 265; and used oil re-refineries.
Federal Government	Federal agency facilities that operate any of the waste management or recovery operations that meet the description of the entities listed under the ''Industry'' category in this table.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that the EPA is now aware could potentially be regulated by this action.

A comprehensive list of Standard Industrial Classification (SIC) codes cannot be compiled for businesses potentially regulated by this action due to the structure of the rule. The rule may be applicable to any business that receives waste, used oil, or used solvent from an off-site location and then manages this material in one of the operations or processes specified in the rule. Thus, for many businesses subject to the rule, the regulated sources (*i.e.,* off-site waste management or recovery operations) are only a small part of the overall manufacturing process or service conducted at the facility. In these cases, the SIC code indicates the primary product produced or service provided at the facility rather than the presence of an off-site waste management or recovery operation at the site which is operated to support the predominate function of the facility. For example, SIC code classifications likely to have off-site waste management or recovery operations at some (but not all) facilities include, but are not limited to, petroleum refineries (SIC code 2911), industrial organic chemical manufacturing (SIC code 286x), plastic materials and synthetics manufacturing (SIC code 282x), and miscellaneous chemical products manufacturing (SIC code 289x). The EPA is also aware of off-site waste management or recovery operations potentially subject to the rule being located at a few facilities listed under SIC codes for refuse systems, waste management, business services, miscellaneous services, and nonclassifiable. Thus, the SIC code alone for a given facility does not determine whether the facility is or is not potentially subject to this rule.

To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in § 63.680 of the rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this document. *World Wide Web (WWW).* The text of today's document will also be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of this action will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules http//www.epa.gov/ttn/oarpg. The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

I. Background

The EPA, under 40 CFR part 63, subpart DD, promulgated the OSWRO NESHAP on July 1, 1996 (61 FR 34140). The OSWRO NESHAP establish standards to control HAP emissions from certain waste management and recovery operations that are not subject to Federal air standards under other subparts in 40 CFR part 61 or 63. Subpart DD specifies the rule's applicability, standards for affected sources, compliance requirements, and reporting and recordkeeping provisions. In addition, subpart DD cross-references other subparts in 40 CFR part 63 for the specific air emissions control requirements to be used for affected tanks, surface impoundments, containers, individual drain systems, and oil-water and organic-water separators. The cross-referenced subparts are Subpart OO, National Emission Standards for Tanks, Level 1; Subpart PP, National Emission Standards for Containers; Subpart QQ, National Emission Standards for Surface Impoundments; Subpart RR, National Emission Standards for Individual Drain Systems; and Subpart VV, National Emission Standards for Oil-Water Separators and Organic-Water Separators. Amendments were made to the final rule on July 20, 1999.

II. Summary of Corrections

Today's changes are described in Table 2 to this preamble for the convenience of the reader.

Table 2

Citation	Change
§ 63.681	Add definition ''Off-site material service'' to amendatory paragraph.
§ 63.684(b)(1)(ii)(A)&(B)	Add the letters ''A'' and ''B'' which were inadvertently left out of July 20, 1999 amendments.
§ 63.685(i) and (i)(4)	Add reference to (i)(4) in (i), intro paragraph, and add (i)(4), which was left out of July 1, 1996 final rule and the July 20, 1999 amendments.
§ 63.691(a)	In the July 20, 1999 amendments, § 63.683(b)(3) was eliminated and § 63.683(d) was added to take its place. The cite in § 63.691(a) referencing § 63.683 was not corrected in the July 1999 amendments to cite § 63.683(d). Today's action corrects this oversight.
§ 63.693(d)(3)(ii), (e)(3)(ii), (f)(3)(iii), and (g)(3)(ii).	The change to the rule removes the ±1 percent accuracy requirement and replaces it with reference to part 60, appendix B, Performance Specification 8 or 9. The EPA received comments that the monitoring requirements in the rule were too vague, in that they did not define what type of monitoring device was acceptable, nor did it establish procedures for determining the accuracy requirement (±1 percent) cited in the rule. The addition of part 60, appendix B, Performance Specification 8 or 9 to the rule will aid sources in choosing and certifying appropriate monitors, as well as establishing quality assurance procedures for maintaining, calibrating and auditing the monitors.

Citation	Change
§ 63.693 (d)(3), (d)(4)(i) and (iii)	This change adds another option to the carbon canister monitoring and replacement requirements consistent with those allowed under other related NESHAP and Resource Conservation and Recovery Act (RCRA) air rules.
§ 63.694(b)(2)(iii)	Correction to subscript of the ''Q_T'' term.
§ 63.694(1)(3)(ii)(A)	Correction to misprinted equation in July 1, 1996 final rule.
Table 2. Applicability of Paragraphs in Subpart A of Part 63—General Provisions to Subpart DD.	§ 63.10(b)(2)(xi) inadvertently left off table. The ''yes'' for this section was added.
§ 63.924(c)(2)	Change reference of § 63.692 to § 63.693. Section 63.692 is reserved.
§ 63.962(b)(3)(ii)	Corrected typographical error ''in accordance.''
§ 63.965(b)	Corrected typographical error ''Standards.''
§ 63.966	Corrected typographical error ''Standards.''
§ 63.1045	Corrected typographical error ''Standards.''

III. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget (OMB). Because the EPA has made a ''good cause'' finding that this action is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of the UMRA. This action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This action does not have substantial direct effects on the States, on the relationship between the national government and the States, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant.

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Public Law No. 104–113), directs EPA to use voluntary consensus standards in their regulatory and procurement 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, business practices) developed or adopted by one or more voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through annual reports to OMB, with explanations when an agency does not use available and applicable voluntary consensus standards.

These final rule amendments provide technical corrections and minor technical amendments to the Off-Site Waste and Recovery Operations NESHAP (Subpart DD). These amendments include two technical standards: Performance Specification 8 (PS–8), Performance Specification for Volatile Organic Compound Continuous Emission Monitoring Systems in Stationary Sources; and Performance Specification 9 (PS–9), Performance Specification for Gas Chromatograph Continuous Emission Monitoring Systems in Stationary Sources which are cited in § 63.693.

Consistent with the NTTAA, the EPA conducted a search for EPA's Performance Specifications 8 and 9. No candidate consensus standards were identified for either performance specification applicable for these amendments. Therefore, EPA is not proposing/adopting any voluntary consensus standards in this rulemaking. Nevertheless, under § 63.8, sources are allowed to apply to EPA for permission to use alternative monitoring in lieu of PS–8 and PS–9.

This technical correction action does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing these rule amendments, the EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of these rule amendments in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. These rule amendments do not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the July 20, 1999 amendments to the final OSWRO rule.

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the Congressional Review Act if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement (5 U.S.C. 808(2)). As stated previously, the EPA has made such a good cause finding, including the reasons therefor, and established an effective date of January 8, 2001. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Off-site waste and recovery operations.

Dated: December 27, 2000.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart DD—National Emission Standards for Hazardous Air Pollutants from Off-Site Waste and Recovery Operations

2. Section 63.684 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 63.684 Standards: Off-site material treatment.

* * * * *

(b) * * *

(1) * * *

(ii) In the case when off-site material streams entering the treatment process are a mixture of off-site material streams having an average VOHAP concentration equal to or greater than 500 ppmw at the point-of-delivery with off-site material streams having average VOHAP concentrations less than 500 ppmw at the point-of-delivery, then the VOHAP concentration of the off-site material must be reduced to a level at the point-of-treatment that meets the performance level specified in either paragraph (b)(1)(ii)(A) or (B) of this section.

(A) Less than the VOHAP concentration limit (C_R) established for the treatment process using the procedure specified in § 63.694(d); or

(B) Less than the lowest VOHAP concentration determined for each of the off-site material streams entering the treatment process as determined by the VOHAP concentration of the off-site material at the point-of-delivery.

* * * * *

3. Section 63.685 is amended by revising paragraph (i) introductory text and adding paragraph (i)(4) to read as follows:

§ 63.685 Standards: Tanks.

* * * * *

(i) The owner or operator who elects to control air emissions by using an enclosure vented through a closed-vent system to an enclosed combustion control device shall meet the requirements specified in paragraphs (i)(1) through (4) of this section.

* * * * *

(4) The owner or operator shall inspect and monitor the closed-vent system and control device as specified in § 63.693.

4. Section 63.691 is amended by revising paragraph (a) to read as follows:

§ 63.691 Standards: Equipment leaks.

(a) The provisions of this section apply to the control of air emissions from equipment leaks for which § 63.683(d) references the use of this section for such air emissions control.

* * * * *

5. Section 63.693 is amended by:

a. Revising paragraphs (d)(3) introductory text and (d)(3)(ii);

b. Revising paragraph (d)(4)(i);

c. Adding paragraph (d)(4)(iii)

d. Revising paragraph (e)(3)(ii);

e. Revising paragraph (f)(3)(iii); and

f. Revising paragraph (g)(3)(ii).

The revisions and addition read as follows:

§ 63.693 Standards: Closed-vent systems and control devices.

* * * * *

(d) * * *

(3) The owner or operator must monitor the operation of the carbon adsorption system in accordance with the requirements of § 63.695(e) using one of the continuous monitoring systems specified in paragraphs (d)(3)(i) through (iii) of this section. Monitoring the operation of a nonregenerable carbon adsorption system (*e.g.,* a carbon canister) using a continuous monitoring system is not required when the carbon canister or the carbon in the control device is replaced on a regular basis according to the requirements in paragraph (d)(4)(iii) of this section.

* * * * *

(ii) A continuous monitoring system to measure and record the daily average concentration level of organic compounds in the exhaust gas stream from the control device. The organic monitoring system must comply either with Performance Specification 8 or 9 in 40 CFR part 60, appendix B. The relative accuracy provision of Performance Specification 8, Sections 2.4 and 3 need not be conducted.

* * * * *

(4) * * *

(i) Following the initial startup of the control device, all carbon in the control device shall be replaced with fresh carbon on a regular, predetermined time interval that is no longer than the carbon service life established for the carbon adsorption system. The provisions of this paragraph (d)(4)(i) do not apply to a nonregenerable carbon adsorption system (*e.g.,* a carbon canister) for which the carbon canister or the carbon in the control device is replaced on a regular basis according to the requirements in paragraph (d)(4)(iii) of this section.

* * * * *

(iii) As an alternative to meeting the requirements in paragraphs (d)(3) and (d)(4)(i) of this section, an owner or operator of a nonregenerable carbon adsorption system may choose to replace on a regular basis the carbon canister or the carbon in the control device using the procedures in either paragraph (d)(4)(iii)(A) or (d)(4)(iii)(B) of this section. For the purpose of complying with this paragraph (d)(4)(iii), a nonregenerable carbon adsorption system means a carbon adsorption system that does not regenerate the carbon bed directly onsite in the control device, such as a carbon canister. The spent carbon removed from the nonregenerable carbon adsorption system must be managed according to the requirements in paragraph (d)(4)(ii) of this section.

(A) Monitor the concentration level of the organic compounds in the exhaust vent from the carbon adsorption system on a regular schedule, and when carbon breakthrough is indicated, immediately replace either the existing carbon canister with a new carbon canister or replace the existing carbon in the control device with fresh carbon. Measurement of the concentration level of the organic compounds in the exhaust vent stream must be made with a detection instrument that is appropriate for the composition of organic constituents in the vent stream and is routinely calibrated to measure the organic concentration level expected to occur at breakthrough. The monitoring frequency must be daily or at an interval no greater than 20 percent of the time required to consume the total carbon working capacity established as a requirement of paragraph (d)(2)(ii)(B) of this section, whichever is longer.

(B) Replace either the existing carbon canister with a new carbon canister or replace the existing carbon in the control device with fresh carbon at a regular, predetermined time interval that is less than the design carbon replacement interval established as a requirement of paragraph (d)(2)(ii)(B) of this section.

(e) * * *

(3) * * *

(ii) A continuous monitoring system to measure and record the daily average concentration level of organic compounds in the exhaust gas stream from the control device. The organic monitoring system must comply either with Performance Specification 8 or 9 in 40 CFR part 60, appendix B. The relative accuracy provision of Performance Specification 8, Sections 2.4 and 3 need not be conducted.

* * * * *

(f) * * *

(3) * * *

(iii) For either type of vapor incinerator, a continuous monitoring system to measure and record the daily average concentration of organic compounds in the exhaust vent stream from the control device. The organic monitoring system must comply either with Performance Specification 8 or 9 in 40 CFR part 60, appendix B. The relative accuracy provision of Performance Specification 8, Sections 2.4 and 3 need not be conducted.

* * * * *

(g) * * *

(3) * * *

(ii) A continuous monitoring system to measure and record the daily average concentration of organic compounds in the exhaust vent stream from the control device. The organic monitoring system must comply either with Performance Specification 8 or 9 in 40 CFR part 60, appendix B. The relative accuracy provision of Performance Specification 8, Sections 2.4 and 3 need not be conducted.

* * * * *

6. Section 63.694 is amended by revising paragraphs (b)(2)(iii) and (l)(3)(ii)(A) to read as follows:

§ 63.694 Testing methods and procedures.

* * * * *

(b) * * *

(2) * * *

(iii) *Calculations.* The average VOHAP concentration (C) on a mass-weighted basis shall be calculated by using the results for all samples analyzed in accordance with paragraph (b)(2)(ii) of this section and the following equation. An owner or operator using a test method that provides species-specific chemical concentrations may adjust the measured concentrations to the corresponding concentration values which would be obtained had the off-site material samples been analyzed using Method 305. To adjust these data, the measured concentration for each individual HAP chemical species contained in the off-site material is multiplied by the appropriate species-specific adjustment factor (f_{m305}) listed in Table 1 of this subpart.

$$C = \frac{1}{Q_T} \times \sum_{i=1}^{n} \left(Q_i \times C_i\right)$$

Where:

C = Average VOHAP concentration of the off-site material at the point-of-delivery on a mass-weighted basis, ppmw.

i = Individual sample ''i'' of the off-site material.

n = Total number of samples of the off-site material collected (at least 4) for the averaging period (not to exceed 1 year).

Q_i = Mass quantity of off-site material stream represented by C_i, kg/hr.

Q_T = Total mass quantity of off-site material during the averaging period, kg/hr.

C_i = Measured VOHAP concentration of sample ''i'' as determined in accordance with the requirements of § 63.694(a), ppmw.

* * * * *

(l) * * *

(3) * * *

(ii) * * *

(A) The following equations shall be used:

$$E_i = K_2 \times Q_i \times \sum_{j=1}^{n} \left(C_{ij} \times M_{ij}\right)$$

$$E_o = K_2 \times Q_o \times \sum_{j=1}^{n} \left(C_{oj} \times M_{oj}\right)$$

Where:

C_{ij}, C_{oj} = Concentration of sample component j of the gas stream at the inlet and outlet of the control device, respectively, dry basis, parts per million by volume.

E_i, E_o = Mass rate of TOC (minus methane and ethane) or total HAP at the inlet and outlet of the control device, respectively, dry basis, kilogram per hour.

M_{ij}, M_{oj} = Molecular weight of sample component j of the gas stream at the inlet and outlet of the control device, respectively, gram/gram-mole.

Q_i, Q_o = Flow rate of gas stream at the inlet and outlet of the control device, respectively, dry standard cubic meter per minute.

K_2 = Constant, 2.494×10^{-6} (parts per million)$^{-1}$ (gram-mole per standard cubic meter) (kilogram/gram) (minute/hour), where standard temperature (gram-mole per standard cubic meter) is 20°C.

* * * * *

7. In Table 2 of Subpart DD, the entry ''63.10(b)(2)(x)'' is revised to read as follows:

TABLE 2 TO SUBPART DD—APPLICABILITY OF PARAGRAPHS IN SUBPART A OF THIS PART 63—GENERAL PROVISIONS TO SUBPART DD

Subpart A	Applies to Subpart DD	Explanation
* * * * * * *		
63.10(b)(2)(x)–(xi)	Yes.	
* * * * * * *		

Subpart PP—National Emission Standards for Containers

8. Section 63.924 is amended by revising paragraph (c)(2) to read as follows:

§ 63.924 Standards—Container Level 3 Controls.

* * * * *

(c) * * *

(2) The closed-vent system and control device shall be designed and operated in accordance with the requirements of § 63.693.

* * * * *

Subpart RR—National Emission Standards for Individual Drain Systems

9. Section 63.962 is amended by revising paragraph (b)(3)(ii)(A) to read as follows:

§ 63.962 Standards.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A) The junction box shall be vented through a closed vent system to a control device except as provided for in paragraph (b)(3)(ii)(B) of this section. The closed vent system and control device shall be designed and operated in accordance with the standards specified in § 63.693.

* * * * *

10. Section 63.965 is amended by revising paragraph (b) to read as follows:

§ 63.965 Recordkeeping requirements.

* * * * *

(b) Owners and operators that use a closed-vent system and a control device in accordance with the provisions of § 63.962 shall prepare and maintain the records required for the closed-vent system and control device in accordance with the requirements of § 63.693.

11. Section 63.966 is revised to read as follows:

§ 63.966 Reporting requirements.

Owners and operators that use a closed-vent system and a control device in accordance with the provisions of § 63.962 shall prepare and submit to the Administrator the reports required for closed-vent systems and control devices in accordance with the requirements of § 63.693.

Subpart VV—National Emission Standards for Oil-Water Separators and Organic-Water Separators

12. Section 63.1045 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 63.1045 Standards—Pressurized separator.

* * * * *

(b) * * *

(3) * * *

(ii) At those times when purging of inerts from the separator is required, and the purge stream is routed to a closed-vent system and control device designed and operated in accordance with the applicable requirements of § 63.693.

[FR Doc. 01–365 Filed 1–5–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[NV 032–FON; FRL–6927–7]

Clean Air Act Reclassification; Nevada—Reno Planning Area; Particulate Matter of 10 Microns or Less (PM–10)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to find that the Reno (Washoe County) Planning Area (RPA) has not attained the annual and 24-hour PM–10 national ambient air quality standards (NAAQS) by the Clean Air Act (CAA) mandated attainment date for moderate nonattainment areas, December 31, 1994. This finding is based on monitored air quality data for the PM–10 NAAQS during the years 1992–1994. As a result of this failure to attain, the RPA will be reclassified under CAA section 188(b)(2) by operation of law as a serious nonattainment area on the effective date of this rule. The State of Nevada will be required to submit a state implementation plan (SIP) revision addressing the CAA provisions for serious areas within 18 months of the reclassification.

EFFECTIVE DATE: This action is effective on February 7, 2001.

ADDRESSES: You can inspect copies of the administrative record for this action at EPA's Region 9 office during normal business hours. U.S. Environmental Protection Agency, Region 9, Air Division, Planning Office (AIR–2), 75 Hawthorne Street, San Francisco, California 94105.

Electronic Availability

This document is also available as an electronic file on EPA's Region 9 Web Page at http://www.epa.gov/region09/air.

FOR FURTHER INFORMATION CONTACT: For monitoring data questions contact Manny Aquitania, U.S. EPA, Region 9, Air Division, Technical Support Office (AIR–7), 75 Hawthorne Street, San Francisco, California 94105, (415) 744–1299, aquitania.manny@epa.gov. For other questions contact Doris Lo, U.S. Environmental Protection Agency, Region 9, Air Division, Planning Office (AIR–2), 75 Hawthorne Street, San Francisco, California 94105, (415) 744–1287, lo.doris@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 22, 2000, EPA proposed to find that the RPA, a moderate PM–10 nonattainment area (40 CFR 81.329) did not attain either the 24-hour or annual PM–10 NAAQS by the required attainment date of December 31, 1994 and, as a result, would be reclassified as a serious area. 65 FR 70326. The proposed finding and resulting reclassification is based on air quality data which revealed violations of the PM–10 NAAQS during 1992–1994. For more background information see the November 22, 2000 proposal at 65 FR 70326. Today's rulemaking provides EPA's responses to public comments and finalizes EPA's proposed action.

II. Public Comments and EPA Responses

In response to the November 22, 2000 proposal, EPA received one comment letter from the Washoe County District Health Department Air Quality Management Division (the District). In general, the District believes that the air quality in the RPA has improved over the past decade and that a reclassification to serious is not indicative of the air quality improvement for the area; however, the District also recognizes that EPA proposed to reclassify the RPA pursuant to the Clean Air Act's statutory requirements. Below are EPA's responses to the District's comments.

Comment 1: The District is concerned that after years of improving PM–10 ambient levels and public outreach efforts promoting their successes, the proposed action will bring into question the credibility of both the District and EPA. Moreover, the District believes that the reclassification of the area to serious nonattainment will require considerable staff resources to be spent on plan preparation and documentation requirements.

In addition, the District does not believe that the serious classification correctly defines the current PM–10 status of the RPA and that maintaining the moderate classification, although it may not be an option provided by the Clean Air Act, would more correctly characterize the area.

Response 1: While the PM–10 ambient levels may have improved over the years, the RPA was violating the PM–10 standard on its CAA attainment deadline of December 31, 1994 and is currently still in violation of the PM–10 standard. The basis for this conclusion and the data supporting it are discussed in detail in the proposed rule. See 65 FR at 70327.

EPA has the responsibility under CAA sections 179(c) and 188(b)(2) to make findings of failure to attain for areas which have not attained the NAAQS by the statutory deadline. Under section 188(b)(2)(A), a moderate PM–10 nonattainment area is reclassified as serious by operation of law if the Administrator finds that the area has failed to attain the NAAQS by the statutory attainment date.

EPA supports the District's efforts to improve the air quality in the Reno area and understands that the District has already spent considerable resources in developing measures that will satisfy the requirements in CAA section 189(b) for a serious PM–10 area. EPA understands that the plan preparation and document requirements can be resource-intensive and difficult, but EPA is encouraged by the District's ongoing efforts and believes that the District's past efforts (*e.g.,* residential wood burning and construction dust control measures) will also help address the serious area planning requirements. These ongoing and past efforts should help the serious area plan preparation and documentation requirements proceed with fewer resources and less difficulty.

Comment 2: The District stated that the lawsuit and accompanying arguments levied by the Sierra Club present the perception that the air quality in the RPA has continually been at a level endangering public health. The District believes this is a

misconception and stresses that they have adopted and are enforcing strict regulations pertaining to residential wood burning and construction dust control, historically two of the largest PM–10 contributors. The District reiterates that the ambient air quality in Washoe County has improved dramatically in the past ten years.

Response 2: EPA agrees that the air quality in the Reno area has improved over the past 10 years. Unfortunately, the area is still in violation of the NAAQS for PM–10 due to a violation recorded in 1999. See ''Table of Sites Violating PM–10 NAAQS in Reno Planning Area, 1997–1999'' in the docket for the proposed rule. As stated in the response to comment 1, EPA supports the District in its efforts to improve the air quality in the Reno area and understands that the District has already spent considerable resources in developing measures that will satisfy the CAA requirements for a serious PM–10 area.

Comment 3: The District states that the RPA attained the annual standard for PM–10 in 1995.

Response 3: As discussed in the proposed rule at 65 FR 70327, attainment for the PM–10 NAAQS is achieved when there are 3 consecutive years of clean data. In 1995, the highest annual arithmetic mean for the RPA was 47 $\mu g/m^3$ found at the Reno-Galetti Way moniter (below the annual PM–10 NAAQS of 50 $\mu g/m^3$). While the RPA did not violate the annual PM–10 NAAQS in 1995 (*i.e.,* had clean data), the RPA still had not attained the annual standard for PM–10 in 1995 due to the annual PM–10 levels in 1993 and 1994. The clean data pointed out by the District are encouraging to EPA, however, the violations recorded in 1999 make an attainment finding impossible at this time.

Comment 4: The District states that the Truckee Meadows Basin did not experience any 24-hour PM–10 violations for 5 years (1994 through 1998). The District states that the RPA measured a violation of the 24-hour standard one day in 1993 and one day six years later in 1999. The District states that the measured 24-hour violations were based on the national every six-day monitoring schedule. For both 1993 and 1999, the District also collected continuous PM–10 data that indicate the RPA did not violate the 24-hour standard during those years. The District claims that if those continuous monitoring instruments were either certified as a federal reference method or if the data were subjected to federal quality assurance procedures by the District, the Truckee Meadows Basin would not, by federal definition, currently be in violation of the standard.

Response 4: In its proposal, EPA explains how the number of violations are determined from monitored exceedance information. In general, for monitors that collect air quality samples less than every day, a recorded exceedance will in effect be prorated, or adjusted, so that the number of expected exceedances for that year will account for the days not sampled. 65 FR 70327. Once this adjustment is made, the number of violations in 1993 and 1999 would be greater than one in each of those years.

The operating agency can avoid the adjustment process for incomplete data by initiating and maintaining everyday sampling for four (4) calendar quarters. 40 CFR part 50, appendix K. However, the continuous PM–10 data collected by the District using a Federal Equivalent Monitor (FEM) during the 1993 and 1999 violation years cannot be considered because quality assurance procedures prescribed in 40 CFR part 58, Appendix A and ''Quality Assurance Handbook for Air Pollution Measurement Systems,'' EPA, August 1998 were not followed.

Comment 5: The District states that the PM10 violation days in 1993 and 1999 were characterized by stagnant air conditions with low carbon monoxide levels. Thus, the District has determined that fugitive dust and residential wood combustion were not the cause, but that re-entrained road dust from wintertime sanding/de-icing operations was the cause of the 24-hour PM–10 violations during 1993 and 1999. The District recognizes the important effect of re-entrained road dust on the area's air quality and is committed to enhancing its efforts to prevent and mitigate this source. The District believes that Washoe County is currently meeting the NAAQS for PM–10 and, with the additional work it plans, the area can maintain attainment for PM–10.

Response 5: EPA believes the District has made a reasonable assessment of the cause of the PM–10 violations in 1993 and 1999 and the Agency expects to see measures to address this issue in its serious area PM–10 plan for the RPA. As stated previously, based on air quality data, EPA does not agree that the RPA is currently meeting the NAAQS for PM–10; however, EPA believes that the District has a good understanding of the controls needed to attain and maintain the PM–10 NAAQS.

III. SIP Requirements for Serious Areas

PM–10 nonattainment areas reclassified as serious under section 188(b)(2) of the CAA are required to submit, within 18 months of the area's reclassification, SIP revisions providing for the implementation of best available control measures (BACM) no later than four years from the date of reclassification. The SIP also must contain, among other things, a demonstration that the implementation of BACM will provide for attainment of the PM–10 NAAQS no later than December 31, 2001. CAA sections 189(b)(1)(A) and 188(e) authorize EPA to grant an extension of that deadline if certain conditions are met. EPA has provided specific guidance on developing serious area PM–10 SIP revisions in an addendum to the General Preamble to title I of the Clean Air Act. See 59 FR 41998 (August 16, 1994).

IV. Summary of Final Action

As stated above, EPA is finalizing its proposed action to find that the RPA failed to attain the PM–10 NAAQS by the December 31, 1994 CAA deadline for moderate areas and, as a result, the RPA will be reclassified as a serious PM–10 nonattainment area on the effective date of this final rule.

V. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget.

Under section 188(b)(2) of the CAA, findings of failure to attain are based solely upon air quality considerations and the subsequent nonattainment area reclassification must occur by operation of law in light of those air quality conditions. These actions do not, in-and-of themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by classifications that, in turn, are triggered by air quality values, findings of failure to attain and reclassifications cannot be said to impose a materially adverse impact on State, local, or tribal governments or communities.

Accordingly, the Administrator certifies that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Similarly, because the finding of failure to attain is a factual determination based on air quality considerations and the resulting reclassification must occur by operation of law and, do not impose any federal

intergovermental mandate, these actions do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). For the same reason, this action also does not significantly or uniquely affect the communities of Indian tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). Also for the same reasons, this finding of failure to attain and resulting reclassification will not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action is also not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. Finally, for the same reason that this finding of failure to attain is a factual determination based on air quality considerations and the resulting reclassification must occur by operation of law, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this finding of failure to attain, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This finding of failure to attain does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 9, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subject in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Dated: December 22, 2000.

John Wise,

Acting Regional Administrator, Region IX.

Part 81, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. In § 81.329, the table for Nevada–PM–10 Nonattainment Areas is amended by revising the entry for ''Washoe County'' to read as follows:

§ 81.329 Nevada.

* * * * *

NEVADA—PM–10

Designated area	Designation		Classification	
	Date	Type	Date	Type
Washoe County Reno Planning Area ..... Hydrographic area 87.	11/15/90	Nonattainment	2/7/01	Serious

* * * * *

[FR Doc. 01–467 Filed 1–5–01; 8:45 am]

BILLING CODE 6560–50–U

Proposed Rules

Federal Register
Vol. 66, No. 5
Monday, January 8, 2001

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–CE–70–AD]

RIN 2120–AA64

Airworthiness Directives; SOCATA—Groupe AEROSPATIALE Model TBM 700 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain SOCATA—Groupe AEROSPATIALE (Socata) Model TBM 700 airplanes equipped with Option No. OPT 70–35–001 (gaseous oxygen system). The proposed AD would require you to incorporate a modification that relocates the oil breather vent location. The proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for France. The actions specified by the proposed AD are intended to prevent oil from entering the gaseous oxygen system service compartment. Such oil contamination could result in a fire or explosion.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before February 10, 2001.

ADDRESSES: Submit comments in triplicate to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–CE–70–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from SOCATA Groupe AEROSPATIALE, Customer Support, Aerodrome Tarbes-Ossun-Lourdes, BP 930–F65009 Tarbes Cedex, France; telephone: (33) (0)5.62.41.73.00; facsimile: (33) (0)5.62.41.76.54; or the Product Support Manager, SOCATA—Groupe AEROSPATIALE, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023; telephone: (954) 894–1160; facsimile: (954) 964–4191. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4146; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How Do I Comment on the Proposed AD?

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments in triplicate to the address specified under the caption **ADDRESSES.** The FAA will consider all comments received on or before the closing date. We may amend the proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of the proposed AD action and determining whether we need to take additional rulemaking action.

Are There Any Specific Portions of the Proposed AD I Should Pay Attention to?

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of the proposed rule that might suggest a need to modify the rule. You may examine all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of the proposed AD.

We are re-examining the writing style we currently use in regulatory documents, in response to the Presidential memorandum of June 1, 1998. That memorandum requires federal agencies to communicate more clearly with the public. We are interested in your comments on whether the style of this document is clearer, and any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at *http://www.plainlanguage.gov.*

How Can I Be Sure FAA Receives My Comment?

If you want us to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 2000–CE–70–AD.'' We will date stamp and mail the postcard back to you.

Discussion

What Events Have Caused This Proposed AD?

The Direction Géneale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified FAA that an unsafe condition may exist on certain Socata Model TBM 700 airplanes equipped with Option No. OPT 70–35–001 (gaseous oxygen system). The DGAC communicates a report of oil entering the gaseous oxygen system service compartment on a Model TBM 700 airplane. In particular, oil was seeping out of the engine oil pump breather.

What Are the Consequences if the Condition Is Not Corrected?

Such oil contamination could result in a fire or explosion.

Is There Service Information That Applies to This Subject?

Socata has issued Service Bulletin No. SB 70–085 71, dated October 2000.

What Are the Provisions of This Service Bulletin?

The service bulletin includes procedures for incorporating Technical Instruction No. OPT70 K076–71 (Modification No. MOD70–119–71) ''OIL PUMP BREATHER''. This modification relocates the oil breather vent location.

What Action Did DGAC Take?

The DGAC classified this service bulletin as mandatory and issued French AD Number 2000–439(A), dated November 15, 2000, in order to assure the continued airworthiness of these airplanes in France.

Was This in Accordance With the Bilateral Airworthiness Agreement?

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Pursuant to this bilateral airworthiness agreement, DGAC has kept FAA informed of the situation described above.

The FAA's Determination and an Explanation of the Provisions of the Proposed AD

What Has FAA Decided?

The FAA has examined the findings of DGAC; reviewed all available information, including the service information referenced above; and determined that:

—The unsafe condition referenced in this document exists or could develop on other Socata Model TBM 700 airplanes of the same type design that are equipped with Option No. OPT 70–35–001 (gaseous oxygen system);

—The actions specified in the previously-referenced service information should be accomplished on the affected airplanes; and

—AD action should be taken in order to correct this unsafe condition.

What Would the Proposed AD Require?

This proposed AD would require you to relocate the oil breather vent location by incorporating Technical Instruction No. OPT70 K076–71 (Modification No. MOD70–119–71) ''OIL PUMP BREATHER''.

Cost Impact

How Many Airplanes Would the Proposed AD Impact?

We estimate that 80 Model TBM 700 airplanes are on the U.S. Registry. Of these 80 airplanes, 4 have a gaseous oxygen system and would be affected by the proposed AD.

What Would Be the Cost Impact of the Proposed AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the proposed modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
4 workhours × $60 = $240	Socata will provide parts free of charge	$240	$240 × 4 = $960.

Regulatory Impact

Would This Proposed AD Impact Various Entities?

The regulations proposed herein 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. Therefore, it is determined that this proposed rule would not have federalism implications under Executive Order 13132.

Would This Proposed AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this proposed action (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) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

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 Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Socata—Groupe Aerospatiale: Docket No. 2000–CE–70–AD

(a) *What airplanes are affected by this AD?* This AD affects Model TBM 700 airplanes, serial numbers 157, 158, 163, 167, and 168, that are:

(1) equipped with Option No. OPT 70–35–001 (gaseous oxygen system); and

(2) certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent oil from entering the gaseous oxygen system service compartment. Such oil contamination could result in a fire or explosion.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
(1) Relocate the oil breather vent location by incorporating Technical Instruction No. OPT70 K076–71 (Modification No. MOD70–119–71 ''OIL PUMP BREATHER'').	Within the next 100 hours time-in-service (TIS) after the effective date of this AD.	In accordance with Socata Service Bulletin No. SB 70–085 71, dated October 2000.
(2) Do not incorporate, on any affected airplane, Option No. OPT 70–35–001 (gaseous oxygen system) without simultaneously incorporating the modification required by paragraph (d)(1) of this AD.	As of the effective date of this AD	Not applicable.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4146; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may obtain copies of the documents referenced in this AD from SOCATA Groupe AEROSPATIALE, Customer Support, Aerodrome Tarbes-Ossun-Lourdes, BP 930—F65009 Tarbes Cedex, France; or the Product Support Manager, SOCATA—Groupe AEROSPATIALE, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. You may examine these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in French AD 2000–439(A), dated November 15, 2000.

Issued in Kansas City, Missouri, on December 29, 2000.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–306 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–CE–26–AD]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company Models 172N, 172P, R172K, 172RG, F172N, F172P, FR172J, and FR172K Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 80–04–08, which currently requires inspecting (one-time) the fuel line and map light switch in the left hand forward door post for chafing or arcing and repairing any damage found on certain Cessna Aircraft Company (Cessna) Model 172N, R172K, F172N, and FR172K airplanes. AD 80–04–08 also required providing at least a 0.50-inch clearance between the map light switch and the fuel line; and installing a switch cover (insulator) over the map light switch. The FAA has determined that chafing between the map light switch and the fuel line could continue to develop over the life of the affected airplanes. The proposed AD would extend the inspections and installation of the switch cover requirement to certain 172N, 172P, R172K, 172RG, F172N, F172P, FR172J, and FR172K series airplanes. The proposed AD would also require replacement of the fuel line, if damaged; and would make the switch cover inspection and replacement repetitive. The actions specified by the proposed AD are intended to detect and correct any chafing between the map light switch and the bordering fuel line, which could result in a fuel leak and an in-flight fire.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule by February 12, 2001.

ADDRESSES: Send three copies of comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–CE–26–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may read comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except holidays.

You may get the service information referenced in the proposed AD from the Cessna Aircraft Company, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 941–7550, facsimile: (316) 942–9008. You may look at this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Clyde Erwin, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209, telephone: (316) 946–4149; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Comments Invited

How Do I Comment on This Proposed AD?

We invite your comments on the proposed rule. You may send whatever written data, views, or arguments you choose. You need to include the rule's docket number and send your comments in triplicate to the address mentioned under the caption **ADDRESSES.** We will consider all comments received by the closing date mentioned above, before acting on the proposed rule. We may change the proposals contained in this notice because of the comments received.

Are There Any Specific Portions of the Proposed AD I Should Pay Attention to?

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of the proposed rule that might call for a need to change the proposed rule. You may examine all comments we receive. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of this proposal.

The FAA is reexamining the writing style we currently use in regulatory documents, in response to the Presidential memorandum of June 1, 1998. That memorandum requires federal agencies to communicate more clearly with the public. We are interested in your comments on the ease of understanding this document, and any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at *http://www.faa.gov/language/.*

How Can I Be Sure FAA Receives My Comment?

If you want to know that we received your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments Docket No. 2000–CE–26–AD.'' We will date stamp and mail the postcard back to you.

Discussion

Has FAA Taken Any Action to This Point?

The FAA issued AD 80–04–08, Amendment 39–3696, February 16, 1980, in order to preclude the possibility of a fuel leak or an in-flight fire due to contact between a map light switch and an adjacent fuel line of certain Cessna Models 172N, R172K, F172N, and FR172K airplanes. AD 80–04–08 requires that you do the following on the affected airplanes:

—Visually inspect the fuel line and map light switch located in the left hand forward door post for chafing or arcing and replace damaged parts as necessary. If not already existing, provide at least a 0.50-inch clearance between the map light switch and the fuel line in accordance with procedures in FAA Advisory Circular 43.13–1A.

—Install a cover (insulator), Cessna Part Number 0511080–1, over the map light switch in accordance with Cessna Single Engine Service Information Letter SE80–3 and Supplement #1 thereto, both dated January 21, 1980.

AD 80–04–08 was the result of instances of chafing between the map light switch and the adjacent fuel line on the affected airplanes. When the chafing caused an electrical short, insulation melted from the map light wire and a hole was burned in the fuel line.

What Has Happened To Necessitate Further AD Action?

Since issuance of AD 80–04–08, FAA has received several reports of incidents of electrical shorts on Cessna Model 172N airplanes. These electrical shorts have resulted because the mounting screws may be elongated or broken out on the affected airplanes or doorpost cover shapes have changed over time. Switch covers may:

—Deteriorate over time;

—Receive damage from service activities,

—Be left off after service activities;

—Not be mounted properly; or

—Not be used in after-market interior installations.

AD 80–04–08 applied to only certain serial numbers and did not cover all of the models that have map light switches in the doorpost.

Is There Service Information That Applies to This Subject?

Cessna issued Service Bulletin SEB00–1, dated January 17, 2000.

What Are the Provisions of This Service Bulletin?

The service bulletin includes procedures for:

—Inspecting for the existence and damage to the cover (insulator) for the doorpost map light switch;

—Installing the cover (insulator) if not installed or found damaged; and

—Replacing the fuel line, if found damaged.

The FAA's Determination and an Explanation of the Provisions of the Proposed AD

What Has FAA Decided?

After examining the circumstances and reviewing all available information related to the incidents described above, we have determined that:

—The unsafe condition referenced in this document exists or could develop on other Cessna models 172N, 172P, R172K, 172RG, F172N, F172P, FR172J, and FR172K airplanes of the same type designs;

—The actions specified in the previously referenced service information should be accomplished on the affected airplanes; and

—AD action should be taken in order to correct this unsafe condition.

What Would This Proposed AD Require?

This proposed AD would supersede AD–80–04–08 with a new AD that would require:

—Repetitively inspecting for the existence and damage to the cover (insulator) for the doorpost map light switch;

—Installing a cover (insulator) if missing or damaged; and

—Replacing the fuel line, if damaged.

Cost Impact

How Many Airplanes Would This Proposed AD Impact?

We estimate that the proposed AD would affect at least 7,750 airplanes.

What Would Be the Cost Impact of the Proposed Initial Inspection for the Affected Airplanes on the U.S. Register?

We estimate that it would take approximately 1 workhour per airplane to do the proposed initial inspection, at an average labor rate of $60 an hour. Based on the figures presented above, the total cost impact of the proposed initial inspection on U.S. operators is estimated to be $465,000, or $60 per airplane. If any parts are required, the estimated cost per airplane for the cover (insulator) is $6.00. The cost for a replacement fuel line varies from $26.00 to $129.00, plus labor, depending on the airplane model.

What About the Cost of Repetitive Inspections?

The FAA has no way of determining the number of repetitive inspections each owner/operator would incur over the life of each of the affected airplanes, or how many covers (insulators) or fuel lines would need to be replaced, so the cost impact is based on the initial inspection.

What Is the Difference Between the Cost Impact of this Proposed AD and the Cost Impact of AD 80–04–08?

The cost impact of the proposed AD is more than currently required by AD 80–04–08. The differences between the proposed AD and AD 80–04–08 are the additional airplane models that would be affected and the repetitive inspections each affected airplane owner/operator would incur over the life of the airplane.

Regulatory Impact

Would This Proposed AD Impact Relations Between Federal and State Governments?

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

Would This Proposed AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this action (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) if put into effect, 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 have placed a copy of the draft regulatory evaluation prepared for this action in the Rules Docket. You may get a copy of it by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Therefore, under the authority delegated to me by the Administrator, the Federal Aviation Administration

(FAA) proposes to amend part 39 of the Federal Aviation Regulations (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. FAA amends § 39.13 by removing Airworthiness Directive (AD) 80–04–08, Amendment 39–3696, and by adding a new AD to read as follows:

Cessna Aircraft Company:

Docket No. 2000–CE–26–AD; Supersedes AD 80–04–08, Amendment 39–3696.

(a) *What airplanes are affected by this AD?* The following Cessna model airplanes, certificated in any category:

Model	Serial No.
172N	17267585 through 17270049; 17270051 through 17274009; 17261445, 17261578, and 17270050.
172P	17274010 through 17276654.
172RG	172RG0001 through 172RG1191; and 691.
F172N	F17201640 through F17202039.
F172P	F17202040 through F17202254.
FR172J	FR17200531 through 17200590.
FR172K ...	FR17200591 through 17200675.
R172K	R1722000 through R1723454; and 680.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes on the U.S. Register must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to continue to detect and correct any chafing between the map light switch and the bordering fuel line, which could result in a fuel leak or an in-flight fire.

(d) *What must I do to address this problem?* To address this problem, unless already done, you must do the following actions:

Actions	Compliance time	Procedures
(1) Inspect the doorpost map light switch insulator (part number 0511080–1) to verify it is installed and (if installed) not damaged.	Initially inspect within the next 100 hours time-in-service (TIS) after the effective date of this AD or within the next 12 calendar months after the effective date of this AD, whichever occurs first. Repetitively inspect thereafter at intervals not to exceed 12 calendar months.	Do this action following the ACCOMPLISHMENT INSTRUCTIONS section of Cessna Service Bulletin SEB00–1, dated January 17, 2000.
(2) If a switch cover (insulator) is not installed or is damaged in any way, install a new insulator (part number 0511080–1).	Before further flight after the inspection where any damage is found or the cover is found missing.	Do this action following the ACCOMPLISHMENT INSTRUCTIONS section of Cessna Service Bulletin SEB00–1, dated January 17, 2000, and the Cessna Manufacturer's Maintenance Manual.
(3) If the fuel line is damaged in any way, install a new fuel line. The replacement fuel line part number varies with aircraft model.	Before further flight after the inspection where any damage is found.	Do this action following the ACCOMPLISHMENT INSTRUCTIONS section of Cessna Service Bulletin SEB00–1, dated January 17, 2000, and the Cessna Manufacturer's Maintenance Manual.

Note 1: The compliance times specified in Cessna Service Bulletin SEB00–1, dated January 17, 2000, are different from those required by this AD. The compliance times in this AD take precedence over those in the service bulletin.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Send your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* You can contact Mr. Clyde Erwin, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209, telephone: (316) 946–4149; facsimile: (316) 946–4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can perform the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from the Cessna Aircraft Company, P. O. Box 7706, Wichita, Kansas 67277; or you may read this document at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

(i) *Does this AD action affect any existing AD actions?* This amendment supersedes AD 80–04–08, Amendment 39–3696.

Issued in Kansas City, Missouri, on December 27, 2000.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–343 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–13–P -

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. 00N–1634]

Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its administrative regulations governing the public disclosure of written information for consideration by an advisory committee at an advisory committee meeting. This action would amend the regulations to state that written information for consideration by an advisory committee at a committee meeting is available for public disclosure, whenever practicable, before or at the time of the meeting. FDA is proposing this action to reflect current FDA policy in conformance with applicable law. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the proposed rule by March 26, 2001. If FDA receives no significant adverse comment on the amendment of these regulations within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period in the direct final rule ends. The direct final rule will be effective 30 days after publication of the confirmation notice in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Discussion

As described more fully in the related direct final rule, FDA's procedures for the administration of advisory committees are set forth in part 14 (21 CFR part 14). Section 14.75(a)(1) states that unless it is otherwise exempt from disclosure, written information for consideration by the committee at the meeting should be available for public disclosure at the same time it is made available to the committee. FDA finds that this provision for simultaneous disclosure is not required by the Federal Advisory Committee Act (5 U.S.C. app. 2) and that compliance with this provision would be detrimental to the advisory committee process. Therefore, the agency is proposing to amend § 14.75(a)(1) to state that the written information for consideration by an advisory committee at any meeting is available for public disclosure, whenever practicable, before or at the time of the meeting.

II. Additional Information

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comments and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends, and FDA intends the direct final rule to become effective 30 days after publication of the confirmation document. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to respond to all of the comments received regarding the rule and, if appropriate, the rule will be finalized under this companion proposed rule using usual notice-and-comment procedures.

For additional information, see the corresponding direct final rule published in the final rules section of this issue of the **Federal Register**. FDA will not provide additional opportunity for comment. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

IV. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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 consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in the other two statutes. This proposed rule is not a significant regulatory action as defined by the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. The agency has considered the effect that this proposed rule will have on small entities. Because the proposed rule will amend only internal agency procedures, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). FDA is not required to prepare a statement of the costs and benefits of this proposed rule because the proposed rule is not expected to

result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

V. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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 proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed 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.

VII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by March 26, 2001. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Two copies of any 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. In the event the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 14 be amended to read as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 is revised to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 14.75 is amended by revising paragraph (a)(1) to read as follows:

§ 14.75 Examination of administrative record and other advisory committee records.

(a) * * *

(1) The written information for consideration by the committee at any meeting: Whenever practicable, before or at the time of the meeting.

* * * * *

Dated: December 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–390 Filed 1–5–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 256

RIN 1010–AC–68

Revision of Requirements Governing Surety Bonds for Outer Continental Shelf Leases.

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: The MMS is proposing to modify requirements governing surety bonds for activities on the Outer Continental Shelf (OCS). These changes will codify the terms and conditions under which a surety will be relieved of responsibility when MMS terminates the period of liability of a bond. Codifying these terms and conditions is necessary to clarify the responsibilities of the lessee and the surety after the lease expires.

DATES: We will consider all comments we receive by March 9, 2001. We will begin reviewing comments then and may not fully consider comments we receive after March 9, 2001.

ADDRESSES: If you wish to comment, you may submit your comments by any one of several methods. You may mail or hand-carry comments (three copies) to the Department of the Interior; Minerals Management Service; Mail Stop 4024; 381 Elden Street; Herndon, Virginia 20170–4817; Attention: Rules Processing Team (RPT). You may also send your comments by e-mail or e-mail attachment. The RPT's e-mail address is: rules.comments@mms.gov.

FOR FURTHER INFORMATION CONTACT: John Mirabella, Engineering and Operations Division, (703) 787–1607.

SUPPLEMENTARY INFORMATION: OCS lessees must comply with regulations governing operations, payments of rents and royalties, and end-of-lease obligations. To ensure that the lessee will be financially able to meet all requirements, including end-of-lease requirements, MMS requires the lessee to post a bond. This rule would amend the provisions of 30 CFR 256.58 concerning the cancellation of a bond.

When the lessee has met all end-of-lease obligations, MMS terminates the liability period of the bond. This amendment addresses situations when the lessee appears to meet all end-of-lease requirements and we later discover that obligations still exist. For example, an audit may reveal that the lessee owes us additional royalty. As another example, a plugged well may start to leak. In either case, the lessee must correct the problem.

In the case of royalties, the liability would be discovered when the audit is conducted after the end of the surety's liability period. By statute, any demand for performance of a monetary obligation must be made within 7 years. In the example of the leaking well, there is not a stipulated time period. Problems associated with plugged wells in the OCS are rare; when they do occur, they are generally discovered within a few years of the plugging activity.

Should the lessee fail to perform a lease obligation, MMS turns to the surety for performance. This rule addresses how long a bond will be held before cancellation to assure availability to cover a problem that is discovered after the liability period on a bond has ended. The current regulation does not set a limit on the period that MMS may continue to hold the bond company responsible for a problem that occurs during the liability period.

OCS wells rarely start to leak following plugging operations. Therefore, we have difficulty predicting when a leak might occur. This notice proposes a period of 7 years (plus such additional time taken for appeals or litigation) during which MMS may hold the bond for claims based upon obligations that accrued during the period of liability. During this period, we will retain security or collateral pledged to MMS in lieu of a surety. The bond will be canceled after 7 years and

any other forms of security will be returned. We believe that a 7-year period will provide adequate protection to the Government and will provide a measure of certainty to bond companies.

The 7-year provision applies to all base bonds, unless we find that less security needs to be retained. The rule would release supplemental bond providers, upon completion of the bonded work, from liability for obligations that accrued before acceptance of the reclamation work, unless we find that potential liability is greater than the amount of the base bond. We will normally release the supplemental bond upon completion of the bonded work because in most cases, we anticipate that the general bond will be sufficient to cover our estimate of potential residual liabilities.

The proposal would not change the provision in 30 CFR 256.58(c) that allows MMS to reinstate your bond. That provision allows us to reinstate your bond as if no cancellation or release had occurred if:

(1) You make a payment under the lease and the payment is rescinded or must be repaid by the recipient because you are insolvent, bankrupt, subject to reorganization, or placed in receivership; or

(2) You represent to us that you have discharged your obligations under the lease and your representation was materially false.

Procedural Matters

Public Comment Procedure: 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 rulemaking record, which we will honor to the extent allowable by law. There may be circumstances in which we would withhold from the rulemaking record a respondent's identity, to the extent 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.

Regulatory Planning and Review (Executive Order 12866)

This document is not a significant rule and is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. This rule, in many important ways, follows aspects of current policy included in the bond form. The rule will also extend that policy to other forms of security such as escrow accounts which are not currently used for base bonds. Since this rule normally will not apply to supplemental bonds without specific action by the Regional Supervisor, the impact of this change is minimal.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. Other agencies are not affected by the bonds and other forms of surety that protect the government's interests.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. This rule will have no effect on the rights of the recipients of entitlements, grants, user fees, or loan programs.

(4) This rule does not raise novel legal or policy issues. The rule more clearly conforms MMS practice to that of the private sector and provides certainty with respect to the cancellation of surety bonds and other lease security.

Regulatory Flexibility (RF) Act

The Department certifies that this rule will not have a significant economic effect on a substantial number of small entities under the RF Act (5 U.S.C. 601 *et seq.*).

This rule will affect lessees and operators of leases on the OCS. This includes about 130 different companies. These companies are generally classified under the North American Industry Classification System (NAICS) code 211111, Crude Petroleum and Natural Gas Extraction, which includes companies that extract crude petroleum and natural gas. For this NAICS code, a small company is one with fewer than 500 employees. Based on these criteria, we estimate that about 54 percent of the companies are considered small. This rule, therefore, affects a substantial number of small entities.

The companies that are considered small have an average of about 15 offshore facilities. We estimate that these small companies have annual sales between $1 million and $380 million.

As discussed in the Regulatory Planning and Review section, we expect this rule to have only minimal effects and, accordingly, we do not expect this rule to have a significant effect on any company, large or small. Under current regulations, when a lessee meets all of the lease requirements, the period of liability ends. If MMS later discovers a problem with the way the work was performed, we will hold the lessee responsible. If the lessee is not able to meet the obligation, we hold the bond company responsible. This regulation establishes a time period during which MMS will hold the bond before cancellation. The codification of a policy on bond cancellation is new. The other change for current practice is that MMS retains pledged securities for the same length of time we have been waiting before canceling surety bonds. While this new provision is needed to ensure consistency of agency practice, the provision will not have a significant effect since companies currently do not use instruments other than surety bonds to meet the basic bond requirement.

This rule will also affect companies that sell surety bonds or provide other types of security to OCS lessees. For those companies, this rule will provide certainty with regard to residual liabilities. Since the provisions in this rule are generally the same as current practice, any effects on bonding companies will be minor. Those minor effects will be reflected in costs charged to oil and gas lessees and will ultimately be borne by oil and gas lessees. These effects are included in the estimates addressing the oil and gas lessees. Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small business about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of MMS, call toll-free (888) 734–3247.

Paperwork Reduction Act (PRA) of 1995

The information collection aspects of this rule remain unchanged. The proposed revisions contain no additional information collection or recordkeeping requirements, and a submission to OMB under the PRA is not required. The OMB has approved the information collection requirements in the current regulations and assigned OMB control number 1010–0006, with a

current expiration date of March 31, 2000.

Federalism (Executive Order 13132)

With respect to Executive Order 13132, the rule does not have Federalism implications. This rule does not substantially and directly affect the relationship between the Federal and State governments. The bonding program is between the Federal Government and the lessees of Federal leases. The bond does not affect obligations between the lessee and any State or local government. This rule does not impose costs on States or localities. State or local governments do not provide bonds and do not need to comply with bonding requirements.

Takings (Executive Order 12630)

With respect to Executive Order 12630, the proposed rule does not have significant Takings implications. A Takings Implication Assessment is not required. The proposed rulemaking is not a governmental action capable of interfering with constitutionally protected property rights.

Civil Justice Reform (Executive Order 12988)

With respect to Executive Order 12988, the 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 Executive Order.

National Environmental Policy Act (NEPA) of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under (5 U.S.C. 804(2)) the SBREFA. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

We do not expect this rule to have a significant effect because, as discussed earlier, this rule would, generally, codify policies already in use. The substantive change for securities other than surety bonds will not have a significant effect because the rule applies to the general bond requirement, and surety bonds are used by almost all MMS lessees to satisfy the base bond requirement.

Unfunded Mandate Reform Act (UMRA) of 1995 (Executive Order 12866)

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required. This is because the rule does not affect State, local, or tribal governments, and the effect on the private sector is small.

List of Subjects in 30 CFR Part 256

Administrative practice and procedure, Continental shelf, Government contracts, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements, Surety bonds.

Dated: December 20, 2000.

Sylvia V. Baca,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Minerals Management Service (MMS) proposes to amend 30 CFR part 256 as follows:

1. The authority citation for part 256 continues to read as follows:

Authority: 43 U.S.C. 1331 *et seq.*; 42 U.S.C. 6213.

2. Section 256.58 is revised to read as follows:

§ 256.58 Termination of the period of liability and cancellation of a bond.

This section defines the terms and conditions under which MMS will terminate the period of liability of a bond or cancel a bond. Terminating the period of liability of a bond ends the period during which obligations continue to accrue but does not relieve the surety of the responsibility for obligations that accrued during the period of liability. Canceling a bond relieves the surety of all liability.

(a) When the surety under your bond requests termination:

(1) The Regional Director will terminate the period of liability under your bond within 90 days after MMS receives the request; and

(2) If you intend to continue operations, or have not completed abandonment, you must provide a replacement bond of an equivalent amount.

(b) If, following the termination of the period of liability of a bond, you provide a replacement bond according to this paragraph, the Regional Director will cancel your terminated bond and the surety that provided your terminated bond will not retain any liability. The Regional Director will cancel your bond if:

(1) The surety issuing the new bond agrees to assume all outstanding liabilities that accrued during the period of liability that was terminated; and

(2) The new bond is equal to or greater than the bond that is to be canceled.

(c) If the period of liability is terminated for a bond but the bond is not replaced by a bond of an equivalent amount, the surety that provided your terminated bond will continue to be responsible for accrued obligations until the obligations are satisfied and for additional periods of time according to paragraph (d) of this section.

(d) At the time your lease expires or is terminated, the surety or sureties that issued the bond(s) covering accrued obligations will continue to be responsible, and the Regional Director will retain other forms of security for the period of time and under the terms shown in the following table:

For the type of bond below	The period of liability will end	Your bond will be cancelled
(1) Base Bonds submitted under § 256.52(a), § 256.53(a), or (b).	When the Regional Director determines that you have met all of your obligations under the lease.	Seven years after the completion of all bonded obligations, or at the conclusion of any appeals or litigation related to your bonded obligations, whichever is later. The Regional Director may: (i) determine that you need less than the full amount of the base bond to meet any possible future problems; and (ii) reduce the amount of your bond or return a portion of your security.

For the type of bond below	The period of liability will end	Your bond will be cancelled
(2) Supplemental bonds submitted under § 256.53(d).	When the Regional Director determines that you have met all your obligations covered by the supplemental bond.	When you meet your bonded obligations, unless the Regional Director: (i) determines that the future potential liability resulting from any undetected problems is greater than the amount of the base bond; and (ii) notifies the provider of the bond that the Regional Director will wait up to 7 years before canceling all or a part of the bond (or longer period as necessary to complete any appeals or judicial litigation related to your bonded obligations).

(e) For all bonds, the Regional Director may reinstate your bond as if no cancellation or release had occurred if:

(1) A person makes a payment under the lease and the payment is rescinded or must be repaid by the recipient because the person making the payment is insolvent, bankrupt, subject to reorganization, or placed in receivership; or

(2) The responsible party represents to MMS that it has discharged its obligations under the lease, and the representation was materially false when the bond was canceled or released.

[FR Doc. 01–120 Filed 1–5–01; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 326

National Reconnaissance Office Privacy Act Program

AGENCY: National Reconnaissance Office, DOD.

ACTION: Proposed rule.

SUMMARY: The National Reconnaissance Office (NRO) is proposing to exempt one Privacy Act systems of records. The system of records is QNRO–23, Counterintelligence Issue Files. The exemptions are intended to increase the value of the systems of records for law enforcement purposes, to comply with prohibitions against the disclosure of certain kinds of information, and to protect the privacy of individuals identified in the systems of records.

DATES: Comments must be received by March 9, 2001 to be considered by the agency.

ADDRESSES: National Reconnaissance Office, Information Access and Release Center, 14675 Lee Road, Chantilly, VA 20151–1715.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Freimann at (703) 808–5029.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

It has been determined that this Privacy Act rule for the Department of Defense does not constitute ''significant regulatory action''. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Act

It has been determined that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act

It has been determined that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act, and 44 U.S.C. Chapter 35.

List of Subjects in 32 CFR Part 326

Privacy.

1. The authority citation for 32 CFR part 326 continues to read as follows:

Authority: Pub. L. 93–579, 88 Stat 1896 (5 U.S.C. 552a).

2. Section 326.17 is proposed to be amended by adding paragraphs (e) as follows:

§ 326.17 Exemptions.

* * * * *

(e) QNRO–23

(1) System name: Counterintelligence Issue Files.

(2) Exemptions: (i) Investigatory material compiled for law enforcement purposes may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of such information, the individual will be provided access to such information except to the extent that disclosure would reveal the identity of a confidential source.

(ii) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

(iii) Therefore, portions of this system of records may be exempt pursuant to 5 U.S.C. 552a(k)(2) and/or (k)(5) from the following subsections of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f).

(3) Authority: 5 U.S.C. 552a(k)(2) and (k)(5).

(4) Reasons: (i) From subsection (c)(3) because to grant access to the accounting for each disclosure as required by the Privacy Act, including the date, nature, and purpose of each disclosure and the identity of the recipient, could alert the subject to the existence of the investigation or prosecutable interest by NRO or other agencies. This could seriously compromise case preparation by prematurely revealing its existence and nature; compromise or interfere with witnesses or make witnesses reluctant to cooperate; and lead to suppression, alteration, or destruction of evidence.

(ii) From subsections (d)(1) through (d)(4), and (f) because providing access to records of a civil or administrative investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(iv) From subsections (e)(4)(G) and (H) because this system of records is compiled for law enforcement purposes and is exempt from the access provisions of subsections (d) and (f).

(v) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. NRO will, nevertheless, continue to publish such a notice in broad generic terms as is its current practice.

(vi) Consistent with the legislative purpose of the Privacy Act of 1974, the NRO will grant access to nonexempt material in the records being maintained. Disclosure will be governed by NRO's Privacy Regulation, but will be limited to the extent that the identity of confidential sources will not be compromised; subjects of an investigation of an actual or potential criminal violation will not be alerted to the investigation; the physical safety of witnesses, informants and law enforcement personnel will not be endangered, the privacy of third parties will not be violated; and that the disclosure would not otherwise impede effective law enforcement. Whenever possible, information of the above nature will be deleted from the requested documents and the balance made available. The controlling principle behind this limited access is to allow disclosures except those indicated above. The decisions to release information from these systems will be made on a case-by-case basis.

Dated: December 21, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–416 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–00–228]

RIN 2115–AE47

Drawbridge Operation Regulations; Mianus River, CT

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the drawbridge operating regulations for the Metro-North Bridge, at mile 1.0, across the Mianus River at Greenwich, Connecticut. This proposed rule would require the bridge to open on signal from 9 p.m. to 5 a.m., after an advance notice is given. The bridge presently does not open for vessel traffic between 9 p.m. and 5 a.m., daily. This action is expected to better meet the reasonable needs of navigation.

DATES: Comments must reach the Coast Guard on or before March 9, 2001.

ADDRESSES: You may mail comments to Commander (obr), First Coast Guard District, Bridge Branch, at 408 Atlantic Avenue, Boston, MA. 02110–3350, or deliver them to the same address between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (617) 223–8364. The First Coast Guard District, Bridge Branch, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the First Coast Guard District, Bridge Branch, 7 a.m. to 3 p.m., Monday through Friday, except, Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. John McDonald, Project Officer, First Coast Guard District, (617) 223–8364.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments or related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD01–00–228), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know if they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the First Coast Guard District, Bridge Branch, at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Metro-North Bridge, mile 1.0, across the Mianus River has a vertical clearance of 20 feet at mean high water and 27 feet at mean low water in the closed position.

The existing operating regulations in 33 CFR 117.209 require the bridge to open on signal from 5 a.m. to 9 p.m., immediately for commercial vessels and as soon as practicable, but no later than 20 minutes after the signal to open is given, for the passage of all other vessel traffic. When a train scheduled to cross the bridge without stopping has passed the Greenwich or Riverside stations and is in motion toward the bridge, the draw shall open as soon as the train has crossed the bridge. From 9 p.m. to 5 a.m., the draw need not be opened for the passage of vessels.

The Coast Guard received a request from a commercial vessel operator requesting a change to the operating regulations for the Metro-North Bridge. The commercial operator requested that the bridge open for vessel traffic during the 9 p.m. to 5 a.m. time period when the bridge is normally closed.

The Coast Guard published a temporary 90 day deviation from the drawbridge operation regulations on April 27, 2000, to provide immediate relief to navigation and to obtain comments from the public concerning this rule. The deviation was in effect from June 7, 2000, through September 4, 2000, during which time, the Metro-North Bridge was required to open on signal, from 9 p.m. to 5 a.m., after a four-hour advance notice was given. No comments were received during the comment period which ended on September 30, 2000. A late comment letter was received from the commercial mariner that requested the rule change. The mariner indicated that his vessel utilized the additional opening time provided by the test deviation and made about 40 transits after 9 p.m. during the test period. The commercial mariner will be adding an additional vessel to his fleet next season which will also require bridge openings after 9 p.m., daily.

The Coast Guard is responsible for the enforcement of the bridge laws and regulations which are intended to prevent any interference with the navigable waters of the United States whether by bridges, dams, dikes or other obstructions to navigation except by express permission of the United States.

The decision as to whether a bridge permit or a drawbridge operation regulation will be issued or promulgated is based upon the effect of the proposed action on navigation to assure that the action provides for the reasonable needs of navigation after full consideration of the effect of the proposed action on the human environment, including the effect on rail and vehicular traffic.

The Coast Guard believes that in the case of the Metro-North Bridge, that changing the bridge operating regulations to require openings between 9 p.m. and 5 a.m. is reasonable because it provides for the needs of navigation, as demonstrated by the demand for bridge openings during the test deviation, and has no effect on rail traffic over the bridge.

Discussion of Proposal

The Coast Guard proposes to revise the operating regulations in 33 CFR 117.209(b) for the Metro-North Bridge by requiring the bridge to open during the 9 p.m. to 5 a.m. time period.

The proposed rule would require the draw to open on signal from April 1 through October 31, from 9 p.m. to 5 a.m., after at least a four-hour advance notice is given and from November 1 through March 30, from 9 p.m. to 5 a.m., after at least a twenty-four hours advance notice is given.

The Coast Guard believes this rule will better meet the reasonable needs of navigation based upon comments received and successful results of the 90-day test deviation.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, Feb. 26, 1979).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation, under paragraph 10e of the regulatory policies and procedures of DOT, is unnecessary. This conclusion is based on the fact that bridges are required to meet the reasonable needs of navigation at all times and that this bridge will only need to be crewed between the hours of 9 p.m. to 5 a.m., when there is a definite navigational need.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under section 5 U.S.C. 605(b), that this proposed rule would not have a significant economic impact on a substantial number of small entities. This conclusion is based upon the fact that the bridge will now be available to open for all vessel traffic, both small entities and commercial operators, at all times.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this proposed rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This proposed rule would not impose an unfunded mandate.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this proposed rule and concluded that, under figure 2–1, paragraph (32)(e), of Commandant Instruction M16475.1C, this proposed rule is categorically excluded from further environmental documentation because promulgation of drawbridge regulations have been found not to have a significant effect on the environment. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. Law 102–587, 106 Stat. 5039.

2. Section 117.209(b) is revised to read as follows:

§ 117.209 Mianus River.

* * * * *

(b) The draw shall open on signal from April 1 through October 31, from 9 p.m. to 5 a.m., after at least a four-hour advance notice is given and from November 1 through March 30, from 9 p.m. to 5 a.m., after at least a twenty-four-hour advance notice is given by calling the number posted at the bridge.

Dated: December 6, 2000.

G.N. Naccara,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 01–435 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 110 and 111

[USCG–2001–8602]

Marine Shipboard Electrical Cable Standards: Incorporation of IEEE Standard 45, 1998 Edition

AGENCY: Coast Guard, DOT.

ACTION: Request for comments.

SUMMARY: The Coast Guard is considering requests to allow merchant vessels to use shipboard cable constructed to meet the requirements in Clause 8 (Cable Construction), Clause 9 (Cable Application), and Clause 10 (Cable Installation) of the Institute of Electrical and Electronics Engineers (IEEE) Standard 45, Recommended Practice for Electrical Installations on Shipboard-1998 edition. The 1998 edition changes the testing requirements for marine shipboard electrical cable from those in the 1983 edition. It also requires third party verification. The Coast Guard requests comments concerning which edition (the 1983 edition, the 1998 edition, or both) should be incorporated by reference.

DATES: Comments and related material must reach the Docket Management Facility on or before March 9, 2001.

ADDRESSES: To make sure your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility [USCG–2001–8602], U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By delivery to 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. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at *http://dms.dot.gov.*

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public will become part of this docket and will be available for inspection or copying at 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 may also find this docket on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this notice, call Dolores Mercier, Project Manager, Office of Design and Engineering Standards (G–MSE), Coast Guard, telephone 202–267–0658, fax 202–267–4816, e-mail *dmercier@comdt.uscg.mil.* For questions on viewing or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, phone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

If you submit written comments, please include your name and address, and identify the docket number for this rulemaking [USCG–2001–8602] and the reason for each comment. You may submit your comments and material by mail, delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES;** but please submit your comments and material by only one means. Please submit all comments and material in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing to the Facility at the address under **ADDRESSES.** If you want acknowledgement of receipt of your comments, please enclose a stamped, self-addressed postcard or envelope. The Coast Guard will consider all comments and materials received during the comment period.

Background and Purpose

On February 8, 2000, a notice of proposed rulemaking was published in the **Federal Register** (65 FR 6111). In this rulemaking the Coast Guard proposed to amend its electrical engineering regulations for merchant vessels by adding alternative cable standards that were equivalent to the existing standards. IEEE Std 45, 1998 edition was not included in that rulemaking as an alternative standard. In the comment process of that notice we received numerous requests from industry to recognize marine shipboard electrical cable that is constructed to IEEE Std. 45–1998 edition. We presently recognize cable constructed to the IEEE Std. 45–1983 edition. The 1998 edition of IEEE Std. 45 changes the testing requirements for marine shipboard electrical cable, and it also requires third party verification. We recognize that there are types of cable found in IEEE Std. 45–1998, that are not found in IEEE Std. 45–1983.

The Coast Guard seeks comments regarding the following three proposals:

1. The Coast Guard should not recognize IEEE Std. 45–1998 edition.
2. The Coast Guard should recognize IEEE Std. 45–1998 edition and should remove the reference to the 1983 edition.
3. The Coast Guard should recognize IEEE Std. 45–1998 edition and should leave the reference to the 1983 edition.

The Coast Guard encourages the public to submit comments on the above three proposals.

Dated: December 27, 2000.

Joseph J. Angelo,

Director of Standards.

[FR Doc. 01–434 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–15–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 23 and 25

[IB Docket No. 00–248, FCC 00–435]

2000 Biennial Regulatory Review

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Commission initiates a review of the procedures governing the processing of

non-routine earth station license applications. The Commission also proposes simplifying the application form for routine earth station licenses. The Commission's objectives are to expedite the review of earth station application, so that earth station operators can provide their services sooner.

DATES: Comments are due on or before March 26, 2001. Reply comments are due on or before April 23, 2001.

Written comments by the public on the proposed information collections are due March 26, 2001. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed information collection(s) on or before April 23, 2001.

ADDRESSES: Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 Fed. Reg. 24,121 (1998). Comments filed through the ECFS can be sent as an electronic file via the Internet to <http://www.fcc.gov/e-file/ecfs.html>. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, and should include the following words in the body of the message, ''get form <your e-mail address>.'' A sample form and directions will be sent in reply.

Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appear in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, The Portals, 445 Twelfth Street, SW., Room TW–A325, Washington, DC 20554.

In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Edward C. Springer, OMB Desk Officer, Room 10236 NEOB, 725 17th Street, NW., Washington, DC 20503 or via the Internet to edward.springer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Steven Spaeth, Satellite and Radiocommunication Division, International Bureau, (202) 418–1539. For additional information concerning the information collection(s) contained in this document, contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking adopted December 11, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Public Reference Room, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Suite 140, 2100 M Street, NW., Washington, DC 20037.

This NPRM contains proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA). It has been submitted to the Office of Management and Budget (OMB) for review under the PRA. OMB, the general public, and other Federal agencies are invited to comment on the proposed information collections contained in this proceeding.

Summary of Notice of Proposed Rulemaking

The Commission has found several cases in which modifying or eliminating rules could facilitate licensing of earth stations, thereby expediting the provision of useful satellite services to the public, without unreasonably increasing the risk of harmful interference to existing earth station or space station operators, or terrestrial wireless operators in shared frequency bands. In particular, we seek comment on the following rule revisions:

(1) Codifying streamlined procedures for case-by-case examination of earth stations using ''non-routine'' antennas, non-routine power levels, or both;

(2) Relaxing some current requirements, such as increasing power and power density limits, and allowing some temporary fixed earth stations to begin operation sooner than is now permitted;

(3) Streamlining the very small aperture terminal (VSAT) rules; and revising the Commission's power level rules to provide for various types of VSAT multiple access methods;

(4) Adopting a simplified license application form for ''routine'' earth stations; and

(5) Other miscellaneous rule revisions.

In addition, the Commission invites parties to propose revisions to part 23 of its rules, governing International Fixed Public Radiocommunication Services.

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (RFA),[1] the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this notice of proposed rulemaking. We request written public comments on this IRFA. Commenters must identify their comments as responses to the IRFA and must file the comments by the deadlines for comments on the notice of proposed rulemaking provided above. The Commission will send a copy of the notice of proposed rulemaking, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. See 5 U.S.C. 603(a). In addition, the Notice of Proposed Rulemaking and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

The Telecommunications Act of 1996 requires the Commission in every even-numbered year beginning in 1998 to review all regulations that apply to the operations or activities of any provider of telecommunications service and to determine whether any such regulation is no longer necessary in the public interest due to meaningful economic competition.

Our objective is to repeal or modify any rules in Part 25 that are no longer necessary in the public interest, as required by Section 11 of the Communications Act of 1934, as amended.

B. Legal Basis

The proposed action is supported by Section 11 of the Communications Act of 1934, as amended, 47 U.S.C. 161.

[1] See 5 U.S.C. 603. The RFA, see, 5 U.S.C. 601 *et seq.,* has been amended by the Contract With America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules May Apply

The RFA directs agencies to provide a description of, and, where feasible, an estimate of, the number of small entities that may be affected by the proposed rules, if adopted.[2] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[3] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[4] A small business concern is one which:

(1) Is independently owned and operated;

(2) Is not dominant in its field of operation; and

(3) Satisfies any additional criteria established by the Small Business Administration (SBA).[5] A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.''[6] Nationwide, as of 1992, there were approximately 275,801 small organizations.[7] ''Small governmental jurisdiction'' generally means ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.''[8] As of 1992, there were approximately 85,006 such jurisdictions in the United States.[9] This number includes 38,978 counties, cities, and towns; of these, 37,566, or 96 percent, have populations of fewer than 50,000.[10] The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, we estimate that 81,600 (91 percent) are small entities. Below, we further describe and estimate the number of small entity licensees that may be affected by the proposed rules, if adopted.

1. Cable Services

The SBA has developed a definition of small entities for cable and other pay television services, which includes all such companies generating $11 million or less in revenue annually. This definition includes cable systems operators, closed circuit television services, direct broadcast-satellite services, multipoint distribution systems, satellite master antenna systems and subscription television services. According to the Census Bureau data from 1992, there were 1,788 total cable and other pay television services and 1,423 had less than $11 million in revenue. The Commission has developed its own definition of a small cable system operator for the purposes of rate regulation. Under the Commission's rules, a ''small cable company,'' is one serving fewer than 400,000 subscribers nationwide.[11] Based on our most recent information, we estimate that there were 1,439 cable operators that qualified as small cable system operators at the end of 1995.[12] Since then, some of those companies may have grown to serve over 400,000 subscribers, and others may have been involved in transactions that caused them to be combined with other cable operators. Consequently, we estimate that there are fewer than 1,439 small entity cable system operators.

The Communications Act also contains a definition of a small cable system operator, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.''[13] The Commission has determined that there are 66,690,000 subscribers in the United States. Therefore, we found that an operator serving fewer than 666,900 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all of its affiliates, do not exceed $250 million in the aggregate.[14] Based on available data, we find that the number of cable operators serving 666,900 subscribers or less totals 1,450.[15] We do not request nor do we collect information concerning whether cable system operators are affiliated with entities whose gross annual revenues exceed $250,000,000, and thus are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

2. International Services

The Commission has not developed a definition of small entities applicable to licensees in the international services. Therefore, the applicable definition of small entity is generally the definition under the SBA rules applicable to Communications Services, Not Elsewhere Classified (NEC).[16] This definition provides that a small entity is expressed as one with $11.0 million or less in annual receipts.[17] According to the Census Bureau, there were a total of 848 communications services providers, NEC, in operation in 1992, and a total of 775 had annual receipts of less than $9.999 million.[18] The Census report does not provide more precise data.

a. Fixed Satellite Transmit/Receive Earth Stations. Currently there are over 7500 authorized fixed satellite transmit/receive earth stations authorized for use in bands shared with the terrestrial fixed service. We do not request or collect annual revenue information, and thus are unable to estimate the number of the earth stations that would constitute a small business under the SBA definition.

b. Mobile Satellite Earth Station Feeder Links. There are two licensees operating in spectrum shared with terrestrial fixed services. We do not request or collect annual revenue information, and thus are unable to estimate of the number of mobile satellite earth stations that would constitute a small business under the SBA definition.

c. Space Stations (Geostationary). Commission records reveal that there are six space station licensees licensed in spectrum shared on a co-primary basis with the terrestrial fixed service in the C- and Ku-bands. We do not request or collect annual revenue information,

[2] 5 U.S.C. 603(b)(3)

[3] Id. 601(6).

[4] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C. 632). Pursuant to the RFA, the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'' 5 U.S.C. 601(3).

[5] Small Business Act, 15 U.S.C. 632 (1996).

[6] 5 U.S.C. 601(4).

[7] 1992 Economic Census, U.S. Bureau of the Census, Table 6 (special tabulation of data under contract to Office of Advocacy of the U.S. Small Business Administration).

[8] 5 U.S.C. 601(5).

[9] U.S. Dept. of Commerce, Bureau of the Census, ''1992 Census of Governments.''

[10] Id.

[11] 47 CFR 76.901(e). The Commission developed this definition based on its determination that a small cable system operator is one with annual revenues of $100 million or less. *Implementation of Sections of the 1992 Cable Act: Rate Regulation, Sixth Report and Order and Eleventh Order on Reconsideration.* 10 FCC Rcd 7393 (1995), 60 FR 10534 (Feb. 27, 1995).

[12] Paul Kagan Associates, Inc., *Cable TV Investor,* Feb. 29, 1996 (based on figures for Dec. 30, 1995).

[13] 47 U.S.C. 543(m)(2).

[14] 47 CFR 76.1403(b).

[15] Paul Kagan Associates, Inc., *Cable TV Investor,* Feb. 29, 1996 (based on figures for Dec. 30, 1995).

[16] An exception is the Direct Broadcast Satellite (DBS) Service, infra.

[17] 13 CFR 120.121, SIC code 4899.

[18] 1992 Economic Census Industry and Enterprise Receipts Size Report, Table 2D, SIC code 4899 (U.S. Bureau of the Census data under contract to the Office of Advocacy of the U.S. Small Business Administration).

and thus are unable to estimate of the number of geostationary space stations that would constitute a small business under the SBA definition.

d. Space Stations (Non-Geostationary). There are four Non-Geostationary Space Station licensees licensed in spectrum shared on a co-primary basis with the terrestrial fixed service in the C- and Ku-bands. We do not request or collect annual revenue information, and thus are unable to estimate of the number of non-geostationary space stations that would constitute a small business under the SBA definition.

3. Auxiliary, Special Broadcast and Other Program Distribution Services

This service involves a variety of transmitters, generally used to relay broadcast programming to the public (through translator and booster stations) or within the program distribution chain (from a remote news gathering unit back to the station). The Commission has not developed a definition of small entities applicable to broadcast auxiliary licensees. Therefore, the applicable definition of small entity is the definition under the Small Business Administration (SBA) rules applicable to radio broadcasting stations (SIC 4832) and television broadcasting stations (SIC 4833). These definitions provide that a small entity is one with either $5.0 million or less in annual receipts for a radio broadcasting station or $10.5 million in annual receipts for a TV station. 13 C.F.R. 121.201, SIC CODES 4832 and 4833. There are currently 3,237 FM translators and boosters, 4913 TV translators.[19] The FCC does not collect financial information on any broadcast facility and the Department of Commerce does not collect financial information on these auxiliary broadcast facilities. We believe, however, that most, if not all, of these auxiliary facilities could be classified as small businesses by themselves. We also recognize that most translators and boosters are owned by a parent station which, in some cases, would be covered by the revenue definition of small business entity discussed above. These stations would likely have annual revenues that exceed the SBA maximum to be designated as a small business (as noted, either $5 million for a radio station or $10.5 million for a TV station). Furthermore, they do not meet the Small Business Act's definition of a ''small business concern'' because they are not independently owned and operated.

4. Microwave Services

Microwave services include common carrier, private operational fixed, and broadcast auxiliary radio services. At present, there are over 13,500 common carrier stations, and approximately 18,000 private operational fixed stations and broadcast auxiliary radio stations in the microwave services in spectrum that is potentially affected by this rulemaking. Additionally, these stations represent the following distinct licensees among the various radio services: LMDS (121), DEMS (2), Common Carrier Fixed (PTP and LTTS) (1028), Private Operational Fixed PTP (1511), and Fixed Broadcast Auxiliary (806).[20] Inasmuch as the Commission has not yet defined a small business with respect to microwave services, we will utilize the SBA's definition applicable to radiotelephone companies—*i.e.*, an entity with no more than 1,500 persons. 13 CFR 121.201, SIC CODE 4812. We estimate, for this purpose, that all of the Fixed Microwave licensees (excluding broadcast auxiliary licensees) would qualify as small entities under the SBA definition for radiotelephone companies.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

None of the proposed rules in this notice are expected to increase the reporting, record keeping and other compliance requirements of any telecommunications carrier.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives: (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

This Notice solicits comment on alternatives for more efficient processing of non-routine earth station applications and simplifying earth station application forms.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

None.

Paperwork Reduction Act: This NPRM contains proposed new and modified information collections. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection(s) contained in this NPRM, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due at the same time as other comments on this NPRM; OMB notification of action is due April 23, 2001. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

OMB Control Number: 3060–0678.

Title: Part 25 of the Commission's Rules Governing the Licensing of, and Spectrum Usage by, Satellite Network Earth Stations and Space Stations

Form No.: FCC Form 312, FCC Form 312 EZ, FCC Form 312–R, FCC Form 312–M, FCC Form 312 Schedule S.

Type of Review: Revision of existing collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 4,560.

Estimated Time Per Response: 2 hours.

Total Annual Burden: 9,120 hours.

Total Annual Costs: $13,838,080.

Needs and Uses: The information collection requirements accounted for in this collection are necessary to determine the technical, legal and financial qualifications of applicants or licensees to operate a station, transfer or assign a license, and to determine whether the authorization is in the public interest, convenience and necessity. Without such information, the Commission could not determine whether to permit respondents to provide telecommunication services in the U.S. The Commission would therefore be unable to fulfill its statutory and responsibilities in accordance with

[19] FCC News Release, *Broadcast Station Totals as of September 30, 1999*, No. 71831 (Jan. 21, 1999).

[20] Results of analysis by FCC ULS contractor in July 2000.

the Communications Act of 1934, as amended, and the obligations imposed on parties to the WTO Basic Telecom Agreement.

Ordering Clauses

Pursuant to Sections 4(i), 7(a), 11, 303(c), 303(f), 303(g), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 157(a), 161, 303(c), 303(f), 303(g), 303(r), that this Notice of Proposed Rulemaking is hereby *Adopted*.

The Commission's Consumer Information Bureau, Reference Information Center, *Shall Send* a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief, Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

Proposed Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission seeks proposals for revisions to part 23 and proposes to amend part 25 of title 47 of the Code of Federal Regulations as follows:

PART 25—SATELLITE COMMUNICATIONS

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

Authority: 47 U.S.C. 701–744. Interprets or applies Sections 4, 301, 302, 303, 307, 309, and 332 of the Communications Act, as amended, 47 U.S.C. Sections 154, 301, 302, 303, 307, 309, 332, unless otherwise noted.

2. Amend § 25.103 by revising paragraphs (b) and (c)(2) to read as follows:

§ 25.103 Definitions.

* * * * *

(b) *Authorized carrier.* The term ''authorized carrier'' means a communications common carrier which is authorized by the Federal Communications Commission under the Communications Act of 1934, as amended, to provide services by means of communications satellites.

(c) * * *

(2) The corporation shall be deemed to be a common carrier within the meaning of section 3(10) of the Communications Act of 1934, as amended.

* * * * *

3. Amend § 25.109 by revising paragraph (c) to read as follows:

§ 25.109 Cross-reference.

* * * * *

(c) Ship earth stations in the Maritime Mobile Satellite Service, see 47 CFR part 80 of this chapter.

4. Amend § 25.110 by revising paragraphs (a) and (b) to read as follows:

§ 25.110 Filing of applications, fees, and number of copies.

(a) Standard application forms applicable to this part may be obtained from the Federal Communications Commission, Forms Distribution Center, by calling 1–800–418–FORM (3676).

(b) Manually filed applications for satellite radio station authorizations governed by this part and requiring a fee shall be mailed or hand-delivered to the locations specified in Part 1, subpart G of this chapter. The addresses for filing and fee amounts for the applications are also listed in the International and Satellite services fee filing guide from the Commission's Forms Distribution Center or by calling 1–800–418–FORM (3676). All other applications shall be submitted to the Secretary, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

* * * * *

5. Amend § 25.111 by revising paragraph (b) to read as follows:

§ 25.111 Additional information.

* * * * *

(b) Applicants, permittees and licensees of radio stations governed by this part shall provide the Commission with all information it requires for the advance publication, coordination and notification of frequency assignments pursuant to the international radio regulations. No protection from interference caused by radio stations authorized by other Administrations is guaranteed unless coordination procedures are timely completed or, with respect to individual administrations, by successfully completing coordination agreements. Any radio station authorization for which coordination has not been completed may be subject to additional terms and conditions as required to effect coordination of the frequency assignments with other Administrations.

6. Amend § 25.113 by revising the section heading and paragraph (a), and removing and reserving paragraph (b) to read as follows:

§ 25.113 Station licenses and launch authority.

(a) Construction permits are not required for satellite earth stations. Construction of such stations may commence prior to grant of a license at the applicant's own risk. Applicants must comply with the provisions of 47 CFR 1.1312 relating to environmental processing prior to commencing construction.

* * * * *

7. Amend § 25.115 by revising paragraphs (a) and (c) to read as follows:

§ 25.115 Application for earth station authorizations.

(a) Transmitting earth stations. Commission authorization must be obtained for authority to operate a transmitting earth station. Applications shall be filed on FCC Form 312 and include the information specified in § 25.130.

* * * * *

(c) Large Networks of Small Antennas operating in the 12/14 GHz frequency bands with U.S.-licensed or non-U.S.-licensed satellites for domestic or international services. Applications to license small antenna network systems operating in the 12/14 GHz frequency band under blanket operating authority shall be filed on FCC Form 312 and Schedule B, for each large (5 meters or larger) hub station, and Schedule B for each representative type of small antenna (less than 5 meters) operating within the network.

* * * * *

8. Revise § 25.117 to read as follows:

§ 25.117 Modification of station license.

(a) Except as provided for in § 25.118 (Modifications not requiring prior authorization), no modification of a radio station governed by this part which affects the parameters or terms and conditions of the station authorization shall be made except upon application to and grant of such application by the Commission.

(b) [Reserved]

(c) Applications for modification of earth station authorizations shall be submitted on FCC Form 312, Main Form and Schedule B, except as set forth in paragraph (e) of this section.

(d) Applications for modifications of space station authorizations shall be filed in accordance with § 25.114, but only those items of information listed in § 25.114(c) that change need to be submitted, provided the applicant certifies that the remaining information has not changed.

(e) Any application for modification of authorization to extend a required date of completion (*e.g.,* begin construction, complete construction, launch, bring into operation) shall be filed on FCC Form 312M (Application for Additional Time to Construct). The application must include a verified statement from the applicant:

(1) That states the additional time is required due to unforeseeable

circumstances beyond the applicant's control, describes these circumstances with specificity, and justifies the precise extension period requested; or

(2) That states there are unique and overriding public interest concerns that justify an extension, identifies these interests and justifies a precise extension period.

(f) Applications for modification of earth station authorizations shall be submitted on FCC Form 312, Main Form and Schedule B, whenever the resulting radiofrequency emissions that would be caused by the modification would cause the power density in a given area to exceed five percent of the radiofrequency exposure limits, such that an environmental assessment statement would be required under § 1.1307(b)(3)(i) of this chapter.

9. Revise § 25.118 to read as follows:

§ 25.118 Modifications not requiring prior authorization.

(a) *Notification required.* Authorized earth station operators may make the following modifications to their licenses without prior Commission authorization, provided that the operators notify the Commission, using FCC Form 312 and Schedule B, within 30 days of the modification:

(1) Licensees may make changes to their authorized earth stations without obtaining prior Commission authorization, provided that they have complied with all applicable frequency coordination procedures in accordance with § 25.251, and the modification does not involve:

(i) An increase in EIRP or EIRP density (both main lobe and side lobe);

(ii) An increase in transmitted power;

(iii) A change in coordinates of more than 1 second in latitude or longitude for stations operating in frequency bands that are shared with terrestrial systems; or

(iv) A change in coordinates of 10 seconds or greater in latitude or longitude for stations operating in frequency bands that are not shared with terrestrial systems.

(v) A change in operations from private carrier to common carrier status.

(2) Equipment in an authorized earth station may be replaced without prior authorization if the new equipment is electrically identical to the existing equipment.

(3) Authorized VSAT earth station operators may add VSAT remote terminals without prior authorization, provided that they have complied with all applicable frequency coordination procedures in accordance with § 25.251, and such modifications do not require prior authorization under § 25.121(e)(3). (VSAT hub earth stations and all remote terminals that are not part of a U.S.-licensed VSAT network are treated like other earth stations for purposes of determining whether they can be modified without prior authorization.)

(b) *Notification not required.* An authorized earth station licensee may add, change or replace transmitters or antenna facilities without prior authorization, provided:

(1) The added, changed, or replaced facilities conform to § 25.209;

(2) The particulars of operations remain unchanged;

(3) Frequency coordination is not required; and

(4) The maximum power and power density delivered into any antenna at the earth station site shall not exceed the values calculated by subtracting the maximum antenna gain specified in the license from the maximum authorized e.i.r.p. and e.i.r.p. density values.

10. Amend § 25.121 by revising paragraphs (a), (c), and (e) to read as follows:

§ 25.121 License term and renewals.

(a) *License term.* Except as provided in paragraphs (b) and (c) of this section, licenses for facilities governed by this part will be issued for a period of 10 years.

* * * * *

(c) *Earth stations.* For earth stations, the license term will be specified in the instrument of authorization. In no case shall this term exceed 15 years.

* * * * *

(e)(1) *Renewal of licenses.* Applications for renewals of earth station licenses must be submitted on FCC Form 312R no earlier than 90 days, and no later than 30 days, before the expiration date of the license. Applications for space station system replacement authorization for non-geostationary orbit satellites shall be filed no earlier than 90 days, and no later than 30 days, prior to the end of the seventh year of the existing license term.

(2) In addition to the requirements of paragraph (e)(1) of this section, applicants seeking renewal of a MET license must include as an attachment to FCC Form 312R a statement of the number of MET units in its network placed into operation.

(3) In addition to the requirements of paragraph (e)(1) of this section, applicants seeking renewal of a VSAT license must include as an attachment to FCC Form 312R a statement of the number of VSAT units in its network placed into operation. If a VSAT licensee does not bring all the VSAT units specified in its license into operation by the time the licensee is renewed, subsequent modification applications to add VSAT units will require prior Commission authorization.

11. Amend § 25.130 by revising paragraph (a) to read as follows:

§ 25.130 Filing requirements for transmitting earth stations.

(a) Applications for a new or modified transmitting earth station facility shall be submitted on FCC Form 312, Main Form and Schedule B, accompanied by any required exhibits. In addition, the applicant shall submit the following information to be used as an ''informative'' in the public notice issued under § 25.151:

(1) A detailed description of the service to be provided, including frequency bands and satellites to be used.

(2) The diameter of the antenna.

(3) Proposed power and power density levels.

(4) Identification of any random access technique, if applicable, as listed in § 25.134(a).

(5) Identification of any rule or rules for which a waiver is requested.

12. Amend § 25.131 by revising paragraphs (a), (b), (h), (i), and (j) to read as follows:

§ 25.131 Filing requirements for receive-only earth stations.

(a) Except as provided in paragraphs (b) and (j) of this section, applications for a license for a receive-only earth station shall be submitted on FCC Form 312, Main Form and Schedule B, accompanied by any required exhibits and the information described in § § 25.130(a)(1) through 25.130(a)(5).

(b) Except as provided in paragraph (j) of this section, receive-only earth stations in the fixed-satellite service that operate with U.S.-licensed satellites may be registered with the Commission in order to protect them from interference from terrestrial microwave stations in bands shared co-equally with the fixed service in accordance with the procedures of § § 25.203 and 25.251.

* * * * *

(h) *Registration term.* Registrations for receive-only earth stations governed by this section will be issued for a period of 15 years from the date on which the application was filed. Applications for renewals of registrations must be submitted on FCC Form 312R (Application for Renewal of Radio Station License in Specified Services) no earlier than 90 days and no later than 30 days before the expiration date of the registration.

(i) Applications for modification of license or registration of receive-only

earth stations shall be made in conformance with § § 25.117 and 25.118. In addition, registrants are required to notify the Commission when a receive-only earth station is no longer operational or when it has not been used to provide any service during any 6-month period.

(j) Receive-only earth stations operating with non-U.S. licensed space stations shall file an FCC Form 312 requesting a license or modification to operate such station. Receive-only earth stations used to receive INTELNET I service from INTELSAT space stations need not file for licenses. See Deregulation of Receive-Only Satellite Earth Stations Operating with the INTELSAT Global Communications Satellite System, Declaratory Ruling, RM No. 4845, FCC 86–214 (released May 19, 1986) available through the International Reference Center, FCC, identified in § 0.453(m) of this chapter.

13. Amend § 25.132 by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 25.132 Verification of earth station antenna performance standards.

(a) All applications for transmitting earth stations must be accompanied by a certificate pursuant to § 2.902 of the chapter from the manufacturer of each antenna that the results of a series of radiation pattern tests performed on representative equipment in representative configurations by the manufacturer demonstrates that the equipment complies with the performance standards set forth in § 25.209. The licensee must be prepared to demonstrate the measurements to the Commission on request.

(b) * * *

(3) Applicants seeking authority to use an antenna that does not meet the standards set forth in § § 25.209(a) and (b), pursuant to the procedure set forth in § 25.220, are required to submit a copy of the manufacturer's range test plots of the antenna gain patterns specified in paragraph (b)(1) of this section.

* * * * *

14. Amend § 25.133 by revising paragraphs (a) and (b) and adding paragraph (e) to read as follows:

§ 25.133 Period of construction; certification of commencement of operation.

(a)(1) Each license for an earth station governed by this part, except for mobile satellite earth station terminals (METs), shall specify as a condition therein the period in which construction of facilities must be completed and station operation commenced. Construction of the earth station must be completed and the station must be brought into operation within 12 months from the date of the license grant except as may be determined by the Commission for any particular application.

(2) Each license for mobile satellite earth station terminals (METs) shall specify as a condition therein the period in which station operation must be commenced. The networks in which the METs will be operated must be brought into operation within 12 months from the date of the license grant except as may be determined by the Commission for any particular application.

(b)(1) Each license for a transmitting earth station included in this part shall also specify as a condition therein that upon the completion of construction, each licensee must file with the Commission a certification containing the following information:

(i) The name of the licensee;

(ii) File number of the application; call sign of the antenna;

(iii) Date of the license;

(iv) A certification that the facility as authorized has been completed and that each antenna facility has been tested and is within 2 dB of the pattern specified in § 25.209, § 25.135 (NVNG MSS earth stations), or § 25.213 (1.6/2.4 GHz Mobile-Satellite Service earth stations). MET licenses shall specify as a condition that the licensee must file a certification that it has begun to provide service;

(v) The date on which the station became operational; and

(vi) A statement that the station will remain operational during the license period unless the license is submitted for cancellation.

(2) For stations authorized under § 25.115(c) (Large Networks of Small Antennas operating in the 12/14 GHz bands) and § 25.115(d) (User Transceivers in the Mobile-Satellite Service), and for mobile satellite earth station terminals (METs), a certificate must be filed when the network is put into operation.

* * * * *

(e) An application for MET authorization shall be filed on FCC Form 312, Main Form and Schedule B. A MET licensee applying to renew its license must follow the procedures provided in § 25.121(e)(2).

15. Amend § 25.134 by revising paragraphs (a), (b), and (d) to read as follows:

§ 25.134 Licensing provisions of very small aperture terminal (VSAT) networks.

(a) All applications for VSAT service in the 12/14 GHz band that meet the following requirements will be routinely processed:

(1) The maximum transmitter power spectral density of a digital modulated carrier into any GSO FSS earth station antenna shall not exceed—14.0—10log(N) dB(W/4 kHz).

(i) For a VSAT network using frequency division multiple access (FDMA) or time division multiple access (TDMA) technique, N is equal to one.

(ii) For a VSAT network using code division multiple access (CDMA) technique, N is the likely maximum number of co-frequency simultaneously transmitting earth stations in the same satellite receiving beam.

(iii) For a VSAT network using contention Aloha multiple access technique, N is equal to two.

(iv) For a VSAT network using contention CDMA/Aloha multiple access technique, N is twice the likely maximum number of co-frequency simultaneously transmitting earth stations in the same satellite-receiving beam without contention.

(2) The maximum GSO FSS satellite EIRP spectral density of the digital modulated emission shall not exceed 6 dB (W/4kHz) for all methods of modulation and accessing techniques.

(3) The maximum hub earth station EIRP shall not exceed 78.3 dBW for all methods of multiple access techniques and supporting VSAT network identified in paragraph (a)(1) of this section.

(4) The maximum transmitter power spectral density of an analog carrier into any GSO FSS earth station antenna shall not exceed −8.0 dB(W/4kHz) and the maximum GSO FSS satellite EIRP spectral density shall not exceed +13.0 dB(W/4kHz).

(b) Each applicant for digital and/or analog VSAT network authorization proposing to use transmitted satellite carrier EIRP densities and/or maximum antenna input power in excess of those specified in paragraph (a) of this Section must comply with the procedures set forth in § 25.220.

* * * * *

(d) An application for VSAT authorization shall be filed on FCC Form 312, Main Form and Schedule B. A VSAT licensee applying to renew its license must follow the procedures provided in § 25.121(e)(3).

16. Amend § 25.138 by adding the following sentence immediately succeeding the last sentence of paragraphs (a)(1) and (a)(2) to read as follows:

§ 25.138 Blanket licensing provisions of GSO FSS earth stations in the 18.58–18.8 GHz (space-to-Earth), 19.7–20.2 GHz (space-to-Earth), 28.35–28.6 GHz (Earth-to-space) and 29.5–30.0 GHz (Earth-to-space) bands.

(a) * * *

(1) * * * N = two for Aloha systems. N = 2 times the likely maximum number of co-frequency simultaneously transmitting earth stations in the receive beam of the satellite for CDMA/Aloha systems.

(2) * * * N = two for Aloha systems. N = 2 times the likely maximum number of co-frequency simultaneously transmitting earth stations in the receive beam of the satellite for CDMA/Aloha systems.

* * * * *

§ 25.141 [Removed]

17. Remove § 25.141.

§ 25.144 [Amended]

18. In § 25.144, remove and reserve paragraph (a)(1).

19. Amend § 25.151 by revising paragraphs (c)(2) and (d), and adding paragraph (e) to read as follows:

§ 25.151 Public notice period.

* * * * *

(c) * * *

(2) For temporary authorization pursuant to § 25.120.

* * * * *

(d) Except as specified in paragraph (e) of this section, no application that has appeared on public notice will be granted until the expiration of a period of thirty days following the issuance of the public notice listing the application, or any major amendment thereto. Any comments or petitions must be delivered to the Commission by that date in accordance with § 25.154.

(e)(1) Applicants seeking authority to operate a temporary fixed earth station pursuant to § 25.277 may consider their applications ''provisionally granted,'' and may initiate operations upon the placement of the complete FCC Form 312 application on public notice, provided that

(i) The temporary fixed earth station will operate only in the conventional Ku-band;

(ii) The temporary fixed earth station's operations will be consistent with all routine-licensing requirements for the conventional Ku-band; and

(iii) The temporary fixed earth station's operations will be limited to satellites on the Permitted Space Station List.

(2) Applications for authority granted pursuant to paragraph (e)(1) of this section shall be placed on public notice pursuant to paragraph (a)(1) of this section. If no comments or petitions are filed within 30 days of the public notice date, the authority granted will be considered a regular temporary fixed earth station authorization as of 30 days after the public notice date. If a comment or petition is filed within 30 days of the public notice date, the applicant must suspend operations immediately pending resolution of the issues raised in that comment or petition.

20. Amend § 25.154 by revising paragraphs (c) and (d) and adding paragraph (e) to read as follows:

§ 25.154 Opposition to applications and other pleadings.

* * * * *

(c) Except for opposition to petitions to deny an application filed pursuant to § 25.220, oppositions to petitions to deny an application or responses to comments and informal objections may be filed 10 days after the petition, comment, or objection is filed and must be in accordance with other applicable provisions of §§ 1.41 through 1.52 of this chapter.

(d) Except for opposition to petitions to deny an application filed pursuant to § 25.220, reply comments by the party that filed the original petition may be filed with respect to pleadings filed pursuant to paragraph (c) of this section within 5 days after the time for filing oppositions has expired unless the Commission otherwise extends the filing deadline and must be in accordance with other applicable provisions of §§ 1.41 through 1.52 of this chapter.

(e) If petition to deny an application filed pursuant to § 25.220 is filed, the applicant must file a statement with the Commission explaining whether the applicant has resolved all outstanding coordination issues raised by the petitioner, within 30 days of the date the petition for deny is filed. This statement must be in accordance with the provisions of §§ 1.41 through 1.52 of this chapter applicable to oppositions to petitions to deny.

21. Revise § 25.201 to read as follows:

§ 25.201 Definitions.

(a) Definitions for terms in subpart C of this part appear in paragraph (b) of this section, and in § 2.1 of this chapter.

(b)(1) *Active satellite.* An earth satellite carrying a station intended to transmit or re-transmit radiocommunication signals.

(2) *Base earth station.* An earth station in the fixed-satellite service or, in some cases, in the land mobile-satellite service, located at a specified fixed point or within a specified area on land to provide a feeder link for the land mobile-satellite service. (RR)

(3) *C-band.* For purposes of this part, the C-band refers specifically to the 3700–4200 MHz downlink and 5925–6425 MHz uplink frequency bands. These paired bands are allocated to the Fixed-Satellite Service and are also referred to as the 4/6 GHz band(s).

(4) *Coordination distance.* For the purposes of this part, the expression ''coordination distance'' means the distance from an earth station, within which there is a possibility of the use of a given transmitting frequency at this earth station causing harmful interference to stations in the fixed or mobile service, sharing the same band, or of the use of a given frequency for reception at this earth station receiving harmful interference from such stations in the fixed or mobile service.

(5) *Earth station.* A station located either on the Earth's surface or within the major portion of the Earth's atmosphere intended for communication:

(i) With one or more space stations; or

(ii) With one or more stations of the same kind by means of one or more reflecting satellites or other objects in space.

(6) *Electronic filing.* The submission of applications, exhibits, pleadings, or other filings to the Commission in an electronic form using Internet or World Wide Web on-line filing forms.

(7) *Equivalent diameter.* When circular aperture reflector antennas are employed, the size of the antenna is generally expressed as the diameter of the antenna's main reflector. When non-reflector or non-circular aperture antennas are employed, an equivalent diameter can be computed for the antenna. The equivalent diameter is the diameter of a hypothetical circular aperture antenna with the same aperture area as the actual antenna. For example, an elliptical aperture antenna with major axis, a, and minor axis, b, will have an equivalent diameter of $[a \times b]^{1/2}$. A rectangular aperture antenna with length, l, and width, w, will have an equivalent diameter of $[(l \times w)/\pi]^{1/2}$.

(8) *Fixed earth station.* An earth station intended to be used at a specified fixed point.

(9) *Fixed-Satellite Service.* A radiocommunication service between earth stations at given positions, when one or more satellites are used; the given position may be a specified fixed point or any fixed point within specified areas; in some cases this service includes satellite-to-satellite links, which may also be operated in the inter-satellite service; the fixed-satellite service may also include feeder links of

other space radiocommunication services. (RR)

(10) *Full transponder.* Radio emissions or transmissions that occupy, or nearly occupy, the entire satellite transponder. C-band and Ku-band satellite systems typically have transponder bandwidths on the order of 36 MHz or more. Single carrier full transponder transmissions can include full motion analog video, thousands of multiplexed voice channels, or high date rates on the order of 50 Mb/s.

(11) *Geostationary satellite.* A geosynchronous satellite whose circular and direct orbit lies in the plane of the Earth's equator and which thus remains fixed relative to the Earth; by extension, a satellite which remains approximately fixed relative to the Earth.

(12) *Inter-Satellite Service.* A radiocommunication service providing links between artificial earth satellites.

(13) *Ku-band.* In this rule part, the Ku-band refers specifically to the 11700–12200 MHz downlink and 14000–14500 MHz uplink frequency bands. These paired bands are allocated to the Fixed-Satellite Service and are also referred to as the 12/14 GHz band(s).

(14) *Land earth station.* An earth station in the fixed-satellite service or, in some cases, in the mobile-satellite service, located at a specified fixed point or within a specified area on land to provide a feeder link for the mobile-satellite service. (RR)

(15) *Land mobile earth station.* A mobile earth station in the land mobile-satellite service capable of surface movement within the geographical limits of a country or continent. (RR)

(16) *Mobile earth station.* An earth station intended to be used while in motion or during halts at unspecified points.

(17) *Mobile-satellite service.* A radiocommunication service:

(i) Between mobile earth stations and one or more space stations, or between space stations used by this service; or

(ii) Between mobile earth stations, by means of one or more space stations. This service may also include feeder links necessary for its operation. (RR)

(18) *Narrowband.* Radio emissions or transmissions with narrow or limited spectral bandwidths. Narrowband satellite transmissions generally provide a single channel or a very limited number of channels. Narrowband satellite transmissions generally have bandwidths of 40 kHz to 5 MHz.

(19) *Non-Voice, Non-Geostationary mobile-satellite service.* A mobile-satellite service reserved for use by non-geostationary satellites in the provision of non-voice communications which may include satellite links between land earth stations at fixed locations.

(20) *1.6/2.4 GHz mobile-satellite service.* A mobile-satellite service that operates in the 1610–1626.5 MHz and 2483.5–2500 MHz frequency bands, or in any portion thereof.

(21) *Passive satellite.* An earth satellite intended to transmit radio communication signals by reflection.

(22) *Permitted space station list.* A list of satellites including all U.S.-licensed satellites and those non-U.S.-licensed satellites for which the Commission has authorized U.S.-licensed earth stations to communicate with that satellite, and the satellite operator has requested the Commission to place its satellite on the Permitted Space Station List.

(23) *Power flux density.* The amount of power flow through a unit area within a unit bandwidth. The units of power flux density are those of power spectral density per unit area, namely watts per hertz per square meter. These units are generally expressed in decibel form as dB(W/Hz/m^2), dB(W/m^2) in a 4 kHz band, or dB(W/m^2) in a 1 MHz band.

(24) *Power spectral density.* The amount of an emission's transmitted carrier power falling within the stated reference bandwidth. The units of power spectral density are watts per hertz and are generally express in decibel form as dB(W/Hz), dB(W/4kHz), or dB(W/1MHz).

(25) *Protection areas.* The geographic regions on the surface of the Earth where United States Department of Defense (''DoD'') meteorological satellite systems or National Oceanic and Atmospheric Administration (''NOAA'') meteorological satellite systems, or both such systems, are receiving signals from low earth orbiting satellites.

(26) *Radiodetermination-satellite service.* A radiocommunication service for the purpose of radiodetermination involving the use of one of more space stations. This service may also include feeder links necessary for its own operation. (RR)

(27) *Routine processing or licensing.* A licensing process whereby applications are processed in an expedited fashion. Such applications must be complete in all regards and consistent with all Commission Rules and must not raise any policy issues. With respect to earth station licensing, an application is ''routine'' only if it conforms to all antenna, power, coordination, radiation hazard, and FAA notification rules, and accesses only ''Permitted Space Station List'' satellites in the C-band or Ku-band frequency bands.

(28) *Satellite Digital Audio Radio Service (''DARS'' or ''SDARS'').* A radiocommunication service in which audio programming is digitally transmitted by one or more space stations directly to fixed, mobile, and/or portable stations, and which may involve complementary SDARS repeaters, telemetry, tracking and control facilities.

(29) *Satellite system.* A space system using one or more artificial earth satellites.

(30) *Spacecraft.* A man-made vehicle which is intended to go beyond the major portion of the Earth's atmosphere.

(31) *Space operation service.* A radiocommunication service concerned exclusively with the operation of spacecraft, in particular space tracking, space telemetry and space telecommand. These functions will normally be provided within the service in which the space station is operating.

(32) *Space radiocommunication.* Any radiocommunication involving the use of one or more space stations or the use of one or more reflecting satellites or other objects in space.

(33) *Space station.* A station located on an object which is beyond, is intended to go beyond, or has been beyond, the major portion of the Earth's atmosphere.

(34) *Space system.* Any group of cooperating earth stations and/or space stations employing space radiocommunication for specific purposes.

(35) *Space telecommand.* The use of radiocommunication for the transmission of signals to a space station to initiate, modify or terminate function of the equipment on a space object, including the space station.

(36) *Space telemetering.* The use of telemetering for the transmission from a space station of results of measurements made in a spacecraft, including those relating to the functioning of the spacecraft.

(37) *Space tracking.* Determination of the orbit, velocity or instantaneous position of an object in space by means of radiodetermination, excluding primary radar, for the purpose of following the movement of the object.

(38) *Temporary fixed earth station.* An earth station operating in the Fixed Satellite Service at a fixed location for less than 6 months. Temporary fixed earth stations are transportable facilities that are moved to the point of operation before communicating. They are often used for emergency restoration of service and news gathering functions. Temporary fixed earth stations do not operate while in motion.

(39) *Terrestrial radiocommunication.* Any radiocommunication other than space radiocommunication or radio astronomy.

(40) *Terrestrial station.* A station effecting terrestrial radiocommunication.

(41) *Wideband.* See *Full transponder.*

§ 25.202 [Amended]

22. In § 25.202, remove and reserve paragraph (a)(2).

23. In § 25.204, revise paragraphs (a) and (b) to read as follows:

§ 25.204 Power limits.

(a) In bands shared coequally with terrestrial radio communication services, the equivalent isotropically radiated power transmitted in any direction towards the horizon by an earth station operating in frequency bands between 1 and 15 GHz, shall not exceed the following limits except as provided for in paragraph (c) of this section:

+40 dBW in any 4 kHz band for $\theta < 0°$

+40+3 θ dBW in any 4 kHz band for $0° < \theta \leq 5°$

where θ is the angle of elevation of the horizon viewed from the center of radiation of the antenna of the earth station and measured in degrees as positive above the horizontal plane and negative below it.

(b) In bands shared coequally with terrestrial radio-communication services, the equivalent isotropically radiated power transmitted in any direction towards the horizon by an earth station operating in frequency bands above 15 GHz shall not exceed the following limits except as provided for in paragraph (c) of this section:

+64 dBW in any 1 MHz band for $\theta<0°$

+64+3 θ dBW in any 1 MHz band for $0°<\theta<5°$

where θ is as defined in paragraph (a) of this section.

* * * * *

24. In § 25.209, revise paragraph (f) to read as follows:

§ 25.209 Antenna performance standards.

* * * * *

(f) An earth station with an antenna not conforming to the standards of paragraphs (a) and (b) of this section will be authorized after February 15, 1985 upon finding by the Commission that unacceptable levels of interference will not be caused under conditions of uniform 2° orbital spacing. An earth station antenna initially authorized on or before February 15, 1985 will be authorized by the Commission to continue to operate as long as such operations are found not to cause unacceptable levels of adjacent satellite interference. In either case, the Commission will impose appropriate terms and conditions in its authorization of such facilities and operations. The applicant has the burden of demonstrating that its antenna not conforming to the standards of paragraphs (a) and (b) of this section will not cause unacceptable interference. This demonstration must comply with the procedures set forth in § 25.220.

* * * * *

25. In § 25.211, revise paragraph (d) and add paragraphs (e), (f), and (g) to read as follows:

§ 25.211 Video transmissions in the Fixed-Satellite Services.

* * * * *

(d) An earth station may be routinely licensed for transmission to full transponder services provided:

(1) In the 6 GHz band, with an antenna equivalent diameter 4.5 meters or greater, the maximum power into the antenna does not exceed 26.5 dBW; or

(2) In the 14 GHz band, with an antenna equivalent diameter 1.2 meters or greater, the maximum power into the antenna does not exceed 27 dBW.

(e) Antennas with an equivalent diameter smaller than those specified in paragraph (d) of this section are subject to the provisions of § 25.220 of this chapter, which may include power reduction requirements. These antennas will not be routinely licensed for transmission of full transponder services.

(f) Each applicant for authorization for video transmissions in the fixed-satellite service proposing to use transmitted satellite carrier EIRP densities, and/or maximum power into the antenna in excess of those specified in § 25.211(d), must comply with the procedures set forth in § 25.220.

(g) The Commission has authority to apply the power level limits in this section to earth station applications for authority to operate in any other FSS frequency band to the extent it deems necessary to prevent unacceptable interference into adjacent satellite systems, to the extent that power limits have not been established elsewhere in this part.

26. Section 25.212 is amended by:

a. Adding the following sentence immediately succeeding the last sentence of paragraph (c).

b. Revising paragraph (d).

c. Adding paragraphs (e) and (f).

The additions and revisions read as follows:

§ 25.212 Narrowband transmissions in the Fixed-Satellite Service.

(c) * * * Antennas with an equivalent diameter smaller than 1.2 meters in the 14 GHz band are subject to the provisions of § 25.220 of this chapter, which may include power reduction requirements.

(d)(1) In the 6 GHz band, an earth station with an equivalent diameter of 4.5 meters or greater may be routinely licensed for transmission of SCPC services if the maximum power densities into the antenna do not exceed +0.5 dBW/4 kHz for analog SCPC carriers with bandwidths up to 200 kHz, and do not exceed -2.7 dBW/4 kHz for narrow and/or wideband digital SCPC carriers. Antennas with an equivalent diameter smaller than 1.2 meters in the 14 GHz band are subject to the provisions of § 25.220, which may include power reduction requirements.

(2) In the 6 GHz band, an earth station with an equivalent diameter antenna of 4.5 meters or greater may be routinely licensed for transmission of SCPC services if the maximum power spectral densities into the antenna do not exceed + 0.5 dB(W/4kHz) for analog SCPC carriers with bandwidths up to 200 kHz and do not exceed $-2.7—10\log(N)$ dB (W/4kHz) for narrow and/or wideband digital SCPC carriers.

(i) For digital SCPC using frequency division multiple access (FDMA) or time division multiple access (TDMA) technique, N is equal to one.

(ii) For digital SCPC using code division multiple access (CDMA) technique, N is the likely maximum number of co-frequency simultaneously transmitting earth stations in the same satellite receiving beam.

(iii) For digital SCPC using contention Aloha multiple access technique, N is equal to two.

(iv) For digital SCPC using contention CDMA/Aloha multiple access technique, N is twice the likely maximum number of co-frequency simultaneously transmitting earth stations in the same satellite-receiving beam without contention.

(e) Each applicant for authorization for narrowband transmissions in the fixed-satellite service proposing to use transmitted satellite carrier EIRP densities, and/or maximum antenna input power densities in excess of those specified in paragraph (c) of this section for Ku-band service, or paragraph (d) of this section for C-band service, respectively, must comply with the procedures set forth in § 25.220.

(f) The Commission has authority to apply the power level limits in this section to earth station applications for authority to operate in any other FSS

frequency band to the extent it deems necessary to prevent unacceptable interference into adjacent satellite systems, to the extent that power limits have not been established elsewhere in this part.

27. Section 25.220 is added to read as follows:

§ 25.220 Non-conforming transmit/receive earth station operations.

(a)(1) This section applies to earth station applications in which:

(i) The proposed antenna does not conform to the standards of § 25.209(a) and § 25.209(b), and/or

(ii) The proposed power density levels are in excess of those specified in § 25.134, § 25.211, or § 25.212, or those derived by the procedure set forth in paragraph (c)(1) of this section, whichever is applicable.

(2) Paragraphs (b) through (e) and (g) of this section apply to the earth station applications described in paragraph (a)(1) of this section, in which the applicant seeks transmit/receive authority.

(3) Paragraphs (f) and (g) of this section applies to the earth station applications described in paragraph (a)(1) of this section in which the applicant seeks transmit-only or receive-only authority.

(4) The requirements for petitions to deny applications filed pursuant to this section are set forth in § 25.154.

(b) If an antenna proposed for use by the applicant does not comply with the antenna performance standards contained in § 25.209(a) and (b), the applicant must provide, as an exhibit to its FCC Form 312 application, the antenna gain patterns specified in § 25.132(b).

(c) If an antenna proposed for use by the applicant does not comply with the performance standards contained in § 25.209(a) and (b), the applicant must meet the requirements of either paragraph (c)(1) or (c)(2) of this section to obtain protection from receiving interference from adjacent satellite operators. The applicant must meet the requirements of either paragraph (c)(1) or (c)(3) of this section to obtain authority to transmit.

(1) The applicant must provide in its Form 312, Schedule B, the power and power density levels that result by reducing the values stated in § § 25.134, 25.211, or 25.212, whichever is applicable, by the number of decibels that the non-compliant antenna fails to meet the antenna performance standard of § 25.209(a) and (b), or

(2) The applicant will not receive protection from adjacent satellite interference from any satellite unless the applicant has provided the affidavits listed in paragraph (d)(1) of this section from the operator of that satellite(s).

(3) The applicant will not be permitted to transmit to any satellite unless the applicant has provided the affidavits listed in paragraph (e)(1) of this section from the operator of that satellite(s).

(d)(1) If an antenna proposed for use by the applicant does not comply with the performance standards contained in § 25.209(a) and (b), the applicant must submit the affidavits listed in paragraphs (d)(1)(i) through (d)(1)(iv) of this section to qualify for protection from receiving interference from other satellite systems. The applicant will be granted protection from receiving interference only with respect to the satellite systems included in the coordination agreements referred to in the affidavit required by paragraph (d)(1)(ii) of this section, and only to the extent that protection from receiving interference is afforded by those coordination agreements.

(i) A statement from the satellite operator acknowledging that the proposed operation of the subject non-conforming earth station with its satellite(s) has the potential to receive interference from adjacent satellite networks that may be unacceptable.

(ii) A statement from the satellite operator that it has coordinated the operation of the subject non-conforming earth station accessing its satellite(s), including its required downlink power density based on the information contained in the application, with all adjacent satellite networks within 6° of orbital separation from its satellite(s), and the operations will not violate any existing coordination agreement for its satellite(s) with other satellite systems.

(iii) A statement from the satellite operator that it will include the subject non-conforming earth station operations in all future satellite network coordinations, and

(iv) A statement from the Earth station applicant certifying that it will comply with all coordination agreements reached by the satellite operator(s).

(2) A license granted pursuant to paragraph (d)(1) of this section will include, as a condition on that license, that if no good faith agreement can be reached between the satellite operator and the operator of a future 2° compliant satellite, the earth station operator shall accept the power density levels that would accommodate the 2° compliant satellite.

(e)(1) An earth station applicant proposing to use transmitted satellite carrier EIRP densities, and/or maximum power into the antenna in excess of the levels in § § 25.134, 25.211, 25.212, or the power density levels derived through the procedure set forth in paragraph (c)(1) of this section, whichever is applicable, shall provide the following affidavits as an exhibit to its earth station application:

(i) A statement from the satellite operator acknowledging that the proposed operation of the subject non-conforming earth station with its satellite(s) has the potential to create interference to adjacent satellite networks that may be unacceptable.

(ii) A statement from the satellite operator that it has coordinated the operation of the subject non-conforming Earth Station accessing its satellite(s), and its corresponding downlink power density requirements (based on the information contained in the application) with all adjacent satellite networks within 6° of orbital separation from its satellite(s), and the operations will not violate any existing coordination agreement for its satellite(s) with other satellite systems.

(iii) A statement from the satellite operator that it will include the subject non-conforming Earth Station power and power densities in all future satellite network coordinations, and

(iv) A statement from the Earth station applicant certifying that it will comply with all coordination agreements reached by the satellite operator(s).

(2) A license granted pursuant to paragraph (e)(1) of this section will include, as a condition on that license, that if no good faith agreement can be reached between the satellite operator and the operator of a future 2° compliant satellite, the earth station operator shall reduce its power to those levels that would accommodate the 2° compliant satellite.

(f)(1) If an earth station applicant requests transmit-only authority, and its proposed antenna does not conform to the standards of § 25.209(a) and (b), it must meet the requirements of paragraphs (b) and (c) of this section.

(2) If an earth station applicant requests transmit-only authority, and its proposed proposed power density levels are in excess of those specified in § § 25.134, 25.211, or 25.212, or those derived by the procedure set forth in paragraph (c)(1) of this section, it must meet the requirements of paragraph (e) of this section.

(3) If an earth station applicant requests receive-only authority, and its proposed antenna does not conform to the standards of § 25.209(a) and (b), it must meet the requirements of paragraphs (b) and (d) of this section.

(g) Applicants filing applications for earth stations pursuant to this section

must provide the following information for the Commission's public notice:

(1) Detailed description of the service to be provided, including frequency bands and satellites to be used.

(2) The diameter of the antenna.

(3) Proposed power and power density levels.

(4) Identification of any random access technique listed in § 25.134(a).

(5) Identification of any rule or rules for which a waiver is requested.

28. In § 25.274, revise paragraph (g) to read as follows:

§ 25.274 Procedures to be followed in the event of harmful interference.

* * * * *

(g) Where the earth station suspected of causing interference to the operations of another earth station cannot be identified or is identified as an earth station operating on a satellite system other than the one on which the earth station suffering undue interference is operating, it is the responsibility of a representative of the earth station suffering harmful interference to contact the control center of other satellite systems. The operator of the earth station suffering undue interference is free to choose any representative to make this contact, including but not limited to the operator of the satellite system on which the earth station is operating. The operator of the earth station suffering undue interference is also free to contact the control center of the other satellite systems directly.

29. Amend § 25.277 by adding paragraph (f) to read as follows:

§ 25.277 Temporary fixed earth station operations.

* * * * *

(f) Filing requirements concerning applications for new temporary fixed earth station facilities operating in frequency bands shared co-equally with terrestrial fixed stations.

(1) When the initial location of the temporary fixed earth station's operation is known, the applicant shall provide, as part of the Form 312 application, a frequency coordination report in accordance with § 25.203 for the initial station location.

(2) When the initial location of the temporary fixed earth station's operation is not known at the time the application is filed, the applicant shall provide, as part of the Form 312 application, a statement by the applicant acknowledging its coordination responsibilities under § 25.277.

PART 25—[AMENDED]

30. Part 25 is amended by removing subpart H.

[FR Doc. 01–88 Filed 1–5–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 10

[Docket No. OST–96–1437; Notice 2000–1]

RIN 2105–AC57

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Proposed rulemaking.

SUMMARY: DOT proposes to exempt from certain provisions of the Privacy Act the record system designed to assist in finding Suspected Unapproved Parts used in aviation, and a record system used to manage the flow of data about commercial motor carriers. An editorial correction is also proposed to some existing language. Public comment is invited.

DATES: Comments are due February 20, 2001.

ADDRESSES: Comments should be addressed to Documentary Services Division, Attention: Docket Section, Room PL401, Docket No. OST–96–1437, Department of Transportation, SVC–124, Washington, DC 20590–0001. Any person wishing acknowledgment that his/her comments have been received should include a self-addressed stamped postcard. Comments received will be available for public inspection and copying in the Documentary Services Division, Room PL401, Department of Transportation Building, 400 Seventh Street, SW., Washington, DC, from 9 AM to 5 PM ET Monday through Friday except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Yvonne Coates, S–80, Office of the Chief Information Officer, Department of Transportation, Washington, DC 20590–0001; telephone: 202–366–6964; fax: 202–366–7024; e-mail: yvonne.coates@ost.dot.gob.

SUPPLEMENTARY INFORMATION: *Aviation.* To assist in the ongoing campaign of the Department's Federal Aviation Administration against defective and dangerous parts being used in aircraft, DOT is establishing a Privacy Act record system in which evidence will be gathered as investigations are conducted (DOT/FAA 852 Suspected Unapproved Parts (SUP) Program). *Motor Carriage.* The recent establishment of DOT's Federal Motor Carrier Safety Administration has led to the development of a management information system (Motor Carrier Management Information System, DOT/FMCSA 001) that will encompass, among other things, safety investigations of commercial motor carriers and of their drivers. In both instances, investigations can result in criminal prosecutions. To facilitate the cooperation of persons who have information relevant to these investigations and who ask for confidentiality as a condition of their providing that information, DOT proposes to exempt these systems from subsections (c)(3) (Accounting for Certain Disclosures), (d) (Access to Records), (e)(4)(G), (H), and (I) (Agency Requirements), and (f) (Agency Rules) of the Privacy Act, 5 USC 552a. If we do not exempt this system from these provisions, persons who are subjects of investigation will be able to learn that they are and who has provided information about them, both of which could well frustrate any investigation.

Finally, in the Appendix, a reference to subsection (e)(4)(I) was inadvertently omitted from, and section (g) was inadvertently included in explanatory paragraph 2 at the end of, paragraph A.

List of subjects in 49 CFR Part 10

Privacy.

Accordingly, DOT proposes to amend the Appendix of Part 10 of 49 CFR as follows:

1. The authority citation for Part 10 continues to read as follows:

Authority: 5 USC 552a; 49 USC 322.

2. Part II A. of the Appendix is amended by adding new paragraphs 17 and 18, and by revising the first sentence of explanatory paragraph 2 to read as follows:

* * * * *

Part II. Specific Exemptions.

A. The following systems of records are exempt from subsections (c)(3) (Accounting of Certain Disclosures), (d) (Access to Records, (e)(4)(G), (H), (I) (Agency Requirements) and (f) (Agency rules) of 5 USC 552a, to the extent that they contain investigatory material for law enforcement purposes in accordance with 5 USC 552a(k)(2):

17. Suspected Unapproved Parts (SUP) Program, maintained by the Federal Aviation Administration (DOT/FAA 852).

18. Motor Carrier Management Information System (MCMIS), maintained by the Federal Motor Carrier Safety Administration (DOT/FMCSA 001).

These exemptions are justified for the following reasons:

* * * * *

2. From subsections (d), (e)(4)(G), (H), and (I), and (f), because granting an individual access to investigative records, and granting him/her access to investigative records with that information, could interfere with the overall law enforcement process by revealing a pending sensitive investigation, possibly identify a confidential source, disclose information that would constitute an unwarranted invasion of another individual's personal privacy, reveal a sensitive investigative technique, or constitute a potential danger to the health or safety of law enforcement personnel. * * *

Dated: December 28, 2000.

Eugene K. Taylor, Jr.,

Deputy Chief Information Officer, U.S. Department of Transportation.

[FR Doc. 01–191 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Annual Notice of Findings on Recycled Petitions

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of review.

SUMMARY: In this notice of review, we announce our recycled petition findings, as required in section 4(b)(3)(C)(i) of the Endangered Species Act of 1972, as amended. When, in response to a petition, we complete a 12-month finding that listing a species is warranted but precluded, we must make a new 12-month finding each year until we publish a proposed rule or make a determination that listing is not warranted. These subsequent 12-month findings are referred to as recycled petition findings.

Information contained in this notice of review is based on our review of the current status and threats to taxa that were the subjects of 27 outstanding warranted but precluded findings. Based on our review, we find that 26 species continue to warrant listing or changes in classification, but these activities are precluded by listing activities of higher priority as determined by our listing priority guidance. One species no longer warrants listing under the Endangered Species Act and, therefore, has been removed from the candidate list.

We announce the availability of listing priority assignment forms for candidate taxa and listing priority determinations for proposed taxa. These documents describe the status and threats that we evaluated in order to assign a listing priority number to each taxon.

We request additional status information that may be available for these candidates as well as information on taxa that we should include as candidates in future updates of this list. We will consider this information in preparing listing documents and future recycled petition findings. This information will help us in monitoring changes in the status of candidate taxa and in conserving these taxa.

DATES: We will accept comments on these recycled petition findings at any time.

ADDRESSES: Submit your comments regarding a particular taxon to the Regional Director of the Region identified as having the lead responsibility for that taxon. You may submit comments of a more general nature to the Chief, Office of Conservation and Classification, Division of Endangered Species, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 420, Arlington, Virginia 22203 (703/358–2171). Written comments and materials received in response to this notice will be available for public inspection by appointment at the appropriate Regional Office listed below.

Information regarding the range, status, and habitat needs of and listing priority assignment for a particular taxon is available for review at the appropriate Regional Office listed below or at the Division of Endangered Species, address listed above.

Region 1. California, Hawaii, Idaho, Nevada, Oregon, Washington, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.

Regional Director (TE), U.S. Fish and Wildlife Service, Eastside Federal Complex, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181 (503/231–6158).

Region 2. Arizona, New Mexico, Oklahoma, and Texas.

Regional Director (TE), U.S. Fish and Wildlife Service, 500 Gold Avenue S.W., Room 4012, P.O. Box 1306, Albuquerque, New Mexico 87102 (505/248–6920).

Region 6. Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming.

Regional Director (TE), U.S. Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, Colorado 80225–0486 (303/236–7400).

FOR FURTHER INFORMATION CONTACT: The Endangered Species Coordinator(s) in the appropriate Regional Office(s) or Nancy Gloman, Chief, Office of Conservation and Classification (703/358–2171).

SUPPLEMENTARY INFORMATION:

Recycled Petition Findings

Background

The Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), provides two mechanisms for considering species for listing. First, the Act places on the Service the duty to identify and propose for listing those species which the Service finds require listing under the standards of section 4(a)(1). We implement this duty through the candidate assessment program. Candidate taxa are those taxa for which we have on file sufficient information on biological vulnerability and threats to support issuance of a proposed rule to list, but issuance of the proposed rule is precluded by other higher priority listing actions. Second, the Act allows the public to petition us to add a species to the Threatened and Endangered Species List. Under section 4(b)(3)(A), when we receive such a petition, we must determine within 90 days, to the maximum extent practicable, whether the petition presents substantial information that listing is warranted (a ''90-day finding''). If we make a positive 90-day finding, under section 4(b)(3)(B) we must make one of three possible findings within 12 months of the receipt of the petition (a ''12-month finding'').

The first possible 12-month finding is that listing is not warranted, in which case we need take no further action on the petition. Second, we may find that listing is warranted, in which case we must promptly publish a proposed rule to list the species. Once we publish a proposed rule for a species, section 4(b)(5) and (6) govern further procedures, regardless of whether or not we issued the proposal in response to a petition. Third, we may find that listing is ''warranted but precluded.'' Such a finding means that immediate publication of a proposed rule to list the species is precluded by higher priority listing proposals, and that we are making expeditious progress to add and remove species from the Lists, as appropriate.

The standard for making a 12-month warranted but precluded finding on a petition to list a species is identical to our standard for making a species a candidate for listing. Therefore, we add all petitioned species subject to such a finding to the candidate list. Pursuant to our Petition Management Guidance, made available on July 9, 1996 (61 FR 36075), we consider a petition to list a

species already on the candidate list to be a second petition and, therefore, redundant. We do not interpret the petition provisions of the Act to require us to make a duplicative finding; therefore, we will not make additional 90-day findings or initial 12-month findings on petitions to list candidate species. Any petition regarding which we have made a warranted but precluded finding is subject to section 4(b)(3)(C)(i), which requires us to make a new 12-month finding on the petition within 12-months of our determination that the petition action was warranted but precluded. These required annual findings on warranted but precluded listing actions are referred to as recycled petition findings. This notice constitutes publication of our recycled petition findings for all species on the candidate list that are currently the subject of an outstanding petition. This notice also constitutes publication of recycled petition findings for species subject to a petition to reclassify an already-listed species from threatened or endangered.

Previous Notices of Review

The Act directed the Secretary of the Smithsonian Institution to prepare a report on endangered and threatened plant taxa, which was published as House Document No. 94–51. We published a notice in the **Federal Register** on July 1, 1975 (40 FR 27823), in which we announced that we would review more than 3,000 native plant taxa named in the Smithsonian's report and other taxa added by the 1975 notice for possible addition to the List of Endangered and Threatened Plants. A new comprehensive notice of review for native plants, that took into account the earlier Smithsonian report and other accumulated information, superseded the 1975 notice on December 15, 1980 (45 FR 82479). On November 28, 1983 (48 FR 53640), a supplemental plant notice of review noted changes in the status of various taxa. We published complete updates of the plant notice on September 27, 1985 (50 FR 39526), February 21, 1990 (55 FR 6184), September 30, 1993 (58 FR 51144), and, as part of combined animal and plant notices, on February 28, 1996 (61 FR 7596), September 19, 1997 (62 FR 49398), and October 25, 1999 (64 FR 57534).

We published earlier comprehensive reviews for vertebrate animals in the **Federal Register** on December 30, 1982 (47 FR 58454), and on September 18, 1985 (50 FR 37958). We published an initial comprehensive review for invertebrate animals on May 22, 1984 (49 FR 21664). We published a combined animal notice of review on January 6, 1989 (54 FR 554), and with minor corrections on August 10, 1989 (54 FR 32833). We again published comprehensive animal notices on November 21, 1991 (56 FR 58804), November 15, 1994 (59 FR 58982), and, as part of combined animal and plant notices, on February 28, 1996 (61 FR 7596), and September 19, 1997 (62 FR 49398). On October 25, 1999 (64 FR 57534), we published our most recent combined candidate notice of review.

This notice is our recycled finding for the taxa that were the subjects of 27 outstanding warranted but precluded findings (21 findings for listing, 1 for withdrawal, and 5 species for reclassification). We also provide notice of revised listing priority numbers and of removal of one species from candidate status. We emphasize that we are not proposing these candidates for listing by this notice, but we anticipate developing and publishing proposed listing rules for these taxa in the future. We encourage State agencies, other Federal agencies, and other parties to give consideration to these taxa in environmental planning. We intend to publish a new combined candidate notice of review that contains all candidate species in March 2001.

Findings on Recycled Petitions

Pursuant to section 4(b)(3)(C)(i), when, in response to a petition, we find that listing a species is warranted but precluded, we must make a new 12-month finding each year until we publish a proposed rule or make a determination that listing is not warranted. These subsequent 12-month findings are referred to as recycled petition findings.

We reviewed the current status and threats to the taxa that were the subjects of the 27 outstanding warranted but precluded findings (22 finding for listing and 5 species for reclassification). As a result of this review, we have made continued warranted but precluded findings for 26 species (21 petitioned for listing and 5 for reclassification) and a not warranted finding for 1 candidate. Below we provide additional information on status changes we have made as a result of our review conducted from October 25, 1999, to date. See Table 1 for a summary of the candidate information. Listing priority assignment form and listing priority determinations for proposed taxon are available by request (see Addresses). These documents describe the status and threats that we evaluated in order to assign priority number to each taxon.

Taxa in Table 1 of this notice are assigned to two status categories, noted in the ''Category'' column at the left side of the table. We identify the taxa for which we have made a continued ''warranted but precluded'' finding on a recycled petition by the code ''C'' in the category column. The ''C'' in this column indicates taxa that are candidates for listing. We identify the one species removed from candidate status with the word ''removed'' in the category column. Candidates are taxa for which we have on file sufficient information on biological vulnerability and threats to support proposals to list them as endangered or threatened. Issuance of proposed rules for these taxa is precluded at present by other higher priority listing actions. We anticipate developing and publishing proposed rules for candidate taxa in the future.

The column labeled ''Priority'' indicates the listing priority number for candidate taxa. We assign this number based on the immediacy and magnitude of threats as well as on taxonomic status. We published a complete description of our listing priority system in a September 21, 1983, **Federal Register** notice (48 FR 43098). We have revised the listing priority numbers for three species, identified by asterisks in this column, as discussed below.

The third column identifies the Regional Office to which you should direct comments or questions (see **ADDRESSES** section). We will consider all information provided in response to this notice of review in deciding whether to propose taxa for listing and when to undertake necessary listing actions. Comments received will become part of the administrative record for the taxa.

Following the scientific name of each taxon (fourth column) is the family designation (fifth column) and the common name, if one exists (sixth column). The seventh column provides the known historical range for the taxon, indicated by postal code abbreviations for States and U.S. territories (many taxa no longer occur in all of the areas listed).

Changes in Listing Priority

Washington ground squirrel (*Spermophilus washingtoni*)

Since the October 25, 1999, publication of the Candidate Notice of Review we have received additional information on the overall decline of the Washington ground squirrel throughout its range and the increased magnitude and permanence of threat that agricultural conversion poses to its continued existence. Based on this information we have changed the listing priority number from 5 (a species with high magnitude, non-imminent threats)

to 2 (a species with high magnitude, imminent threats).

Betts (1990, 1999) documented the curtailment in the range of the Washington ground squirrel to three disjunct areas. His surveys on historic and documented occurrences focused on the perimeters of the range with the intent of evaluating reductions in numbers of colonies and the size of the current range. Although Betts' surveys do not provide an exhaustive survey of all potential squirrel locations or numbers of individuals, they do provide a good estimate of the distribution and decline of Washington ground squirrels in Oregon and Washington. Betts found that the species had disappeared from 73.8 percent of the sites in Washington and 76.9 percent of the sites in Oregon. In addition, Betts (1990) subjectively evaluated the vulnerability to extinction of each of the remaining known colonies based on colony size, isolation, land ownership, and threat from human activity.

In 1990, Betts predicted that approximately 29 percent of all colonies were highly vulnerable to extinction (19 percent in Oregon, 35 percent in Washington); 31 percent were moderately vulnerable (39 percent in Oregon, 25 percent in Washington); and 40 percent had low vulnerability (42 percent in Oregon, 39 percent in Washington). Since this prediction follow up monitoring has shown that Betts' predictions proved correct, and many colonies classified as highly vulnerable were no longer present by 1999 (Betts 1999).

In addition to new information regarding population declines, recent reports indicate that agricultural conversion permanently eliminates Washington ground squirrel habitat and use. Prior to this new information it was thought that areas could again be recolonized. However, because the squirrel is so closely tied to deep, silty soils, specifically Warden soils on the Boeing Tract (Greene 1999), the tilling and other mechanisms involved in conversion of shrub-steppe habitats to agricultural crop production not only destroys the species' food source, but it also renders the soils necessary for burrowing unuseable and irretrievably modified. Washington ground squirrels are not found in tilled croplands (Carlson *et al.* 1980; Betts 1990, 1999; Quade 1994), nor have they been located in undeveloped areas between irrigated crops (CH2M Hill 2000). As a result of these studies it is clear that once areas have been modified they are no longer able to support Washington ground squirrels not only in the present but in the future as well, thus increasing the magnitude of these threats. In additional there is currently proposed development for areas which currently support the highest known concentration of Washington ground squirrels (Greene 1999), this proposed development increases the immediacy of the threats. Great Basin population of the Columbia spotted frog (*Rana* luteiventris),

We have changed the listing priority number from 9 (a population with moderate magnitude, imminent threats) to 3 (a population with high magnitude, imminent, threats). This is based on a decrease in survival of newly hatched and adult frogs and an increase in the magnitude of the threats to the Great Basin population of the Columbia spotted frogs from introduction of non-native fishes, grazing, and lack of regulatory mechanisms.

Columbia spotted frogs in Idaho have shown significant declines in the last years through reductions in both newly hatched and adult survival. At the largest known site in Idaho, frog numbers have shown a significant decline, although eggs masses were identified there was little or no survival of these eggs to tadpoles or adult. One other known population appears to be extirpated due to the loss of beaver activity, with only one male frog observed in 1999. Monitoring at another site that has been protected from grazing (although the spring and source of water has been developed for off-site water access by livestock), has had no documented recruitment in the last three years (all frogs have been pit-tagged at this site) and may disappear as the existing breeding females age.

The introduction of non-native salmonid and bass species for recreational fishing may have negatively affected frog species throughout the United States. The negative effects of predation of this kind are difficult to document, particularly in open stream systems. However, significant negative effects of predation on frog populations in lake systems have been documented through research (Hayes and Jennings 1986, Pilliod *et al.* 1996). The stocking of non-native fishes is common throughout the waters of the Great Basin. Given the recent declines of frog populations and continued stocking of non-native fishes, we believe the magnitude of this threat has increased.

Grazing has also been identified as a threat because it removes vegetative cover and shrubs eliminating shelter necessary for frogs to avoid predators and UV-B radiation; in addition, cattle tramping on the banks and within the water can cause changes in water temperature and water chemistry, causing a reduction in prey availability. Development of springs to provide water for grazing has resulted in loss of surface water, reduced areas occupied during the winter by dormant spotted frogs, and result in loss of continuous surface flows between foraging and wintering sites.

There are large areas in the northeastern part of Nevada and southeastern Oregon where there has been little to no monitoring or surveying of occupied sites, and no actions have been taken yet to protect populations or restore habitats in that region. Even in Idaho, where the status of populations are better known, neither the Bureau of Land Management, on which some of the known populations are found, nor the State of Idaho have implemented conservation measures to control grazing within wetlands/riparian habitats, stocking of non-native fish, or the development of springs in a manner consistent with Columbia spotted frog conservation. The lack of effective conservation actions, coupled with the recent declines, has resulted in an increase in the magnitude and immediacy of the threat since our last evaluation.

We also are correcting the historical range for the Great basin population of the Columbia spotted frog. In the October 25, 1999, **Federal Register** it was erroneously published as U.S.A. (AK, CA, ID, MT, NV, OR, UT, WA, WY), Canada. The correct historical range should read U.S.A. (NV, ID, OR); this has been changed in Table 1 of this notice.

Oregon spotted frog (Rana pretiosa)

The listing priority number was erroneously published as 6 in the 1999 CNOR. The listing priority number was changed from 6 (a subspecies with moderate magnitude, imminent threats) to 2 (a full species, with high magnitude, imminent threats) in the 1997 CNOR when the Oregon spotted frog received full species recognition, and should have been continued as 2 in the 1999 CNOR.

Threats are considered imminent because the remaining populations have experienced high mortality rates in recent years and the remaining populations are isolated from each other and face multiple threats. It has unique egg-laying habits that make egg masses susceptible to freezing and drought; two to three years of drought could eliminate a population. Communal egg laying at traditional sites makes the Oregon spotted frog especially vulnerable to habitat loss. The best documented population, at Conboy Lake National Wildlife Refuge, experienced a

22.6 percent decline in egg mass counts from 1998 to 1999.

At the time of the original petition in 1989 to list the spotted frog we used Thompson's (1913) description of two subspecies, *Rana pretiosa pretiosa* and *Rana pretiosa luteiventris,* as our classification. However, this subspecific classification was no longer recognized at the time of the initial warranted but precluded 12-month finding in 1993, when we identified 5 distinct vertebrate populations of the spotted frog. This differentiation was based on geographic and climatic separation, and supported by genetic information. The confusing taxonomy resulting from reliance on morphological differences is being clarified using recently developed biochemical techniques for genetic analyses. Green (1986) used an analysis of proteins to determine that *Rana pretiosa* was a complex of at least 2 species (Green 1986, Green *et al.* 1996). Further protein and statistical analyses of 20 morphological measurements provided additional information to help define the ranges of these 2 species (Green *et al.* 1997), now known as the Oregon spotted frog and the Columbia spotted frog.

Finding on Candidate Removals

Swift Fox *(Vulpes velox)*

In 1994, the Swift Fox Conservation Team (SFCT) was formed by the 10 States within the historic range of the swift fox, Canada, and several Federal agencies, including the Service. This team has drafted the Swift Fox Conservation Assessment and Conservation Strategy (CACS)(Kahn *et al.* 1997), and produced five annual reports (Allen *et al.* 1995, Giddings 1997, Luce and Lindzey 1996, Roy 1998, Schmitt 2000) which have provided additional information regarding the distribution and abundance of the species. Swift fox distribution is more widespread than we originally concluded in our initial warranted but precluded 12-month finding in 1995. The species occurs in 9 of the 10 States within the historic range, and in approximately 40 percent of its historic range. Evaluations conducted by the SFCT have demonstrated nearly continuous distribution of swift fox populations from Wyoming south throughout eastern Colorado, western Kansas, the Oklahoma Panhandle, eastern New Mexico, and in two or three counties in the extreme northern panhandle of Texas. Scattered populations can also be found in Montana, South Dakota, and Nebraska.

The swift fox also appears to be more general in its habitat requirements than we concluded in the initial 12-month finding published June 16, 1995 (60 FR 31663). Information gathered by the SFCT in Kansas and Colorado demonstrates that the swift fox has been able to adapt to a mixed prairie-agricultural landscape.

Adaptability to various habitat types was further demonstrated in Wyoming where the swift fox was found to occupy sagebrush-grassland and sagebrush-greasewood habitat types with topography ranging from flat to badland-like terrain. Other habitat types used by swift fox included the sandhills of Nebraska and pinon-juniper habitat in Colorado and Oklahoma (Hoagland, Swift Fox Conservation Team Chair, *in litt.* 2000). Historic and recent data indicate that the swift fox can be regionally adaptable in its food preferences and is not dependent upon prairie dog communities to provide forage across most of its current range (Allen *et al.* 1995, Giddings 1997, Luce and Lindzey 1996, Roy 1998, Schmitt 2000).

As a result of new information, originally identified threats are no longer applicable for the following reasons: (1) The swift fox is more abundant and widely distributed than previously thought, and (2) the species is more flexible in its habitat requirements than originally believed.

The Service's 1995 12-month Finding concluded that most remaining swift fox populations occurred in marginally viable populations in scattered, isolated pockets of remnant short and mid-grass prairie habitat. Moreover, we concluded that most remaining grassland in the western Great Plains consisted of a mixed cropland/grassland mosaic which did not favor swift fox use. However, extensive rangelands still exist as predominately grassland environments in the swift fox's historic range and although some conversion to agriculture use is still occurring, it is at a much lower rate than in previous years. Additionally, recent studies indicate that the swift fox is more flexible than we previously determined in its habitat requirements and can utilize areas with mixed land uses (Allen *et al.* 1995, Giddings 1997, Luce and Lindzey 1996, Roy 1998, Schmitt 2000).

In the original finding we believe that commercial trapping of furbearers within the range of the swift fox may have been a threat. However, available information suggests that this harvest has not limited swift fox populations. We have also found no indication that parasites or diseases are significant factors in the population dynamics of wild foxes. In the 12-month finding, we cited a lack of regulatory mechanisms to protect the swift fox. Since then, 10 State wildlife agencies within the historic range of the swift fox have committed significant resources towards the conservation of the species with the development of the CACS (Kahn *et al.* 1997). The primary objectives of the CACS have largely been completed with the organization of the SFCT, the acquisition of State and Federal funding, the generation of annual reports, and the determination of current distribution of the swift fox.

Based on our reexamination of these threats, and pursuant to our analysis of the five factors under section 4(a)(1), we find that the swift fox is not likely to become in danger of extinction throughout all or a significant portion of its range in the foreseeable future. Therefore, we find that the petitioned action is not warranted and are removing the swift fox from the candidate list.

Findings on Reclassification From Threatened to Endangered

We have also previously made warranted but precluded findings for petitions that sought to reclassify species status listed as threatened to endangered. Because these species are already listed, they are not candidates for listing, and so are not included in Table 1. However, this notice also constitutes the recycled petition findings for these species. We find that reclassification from threatened to endangered status is currently warranted but precluded for:

(1) North Cascades Ecosystem grizzly bear (*Ursus arctos horribilis*) population (Region 6);

(2) Cabinet-Yaak grizzly bear populations (Region 6);

(3) Selkirk grizzly bear populations (Region 6);

(4) spikedace (*Meda fulgida*) (Region 2); and

(5) loach minnow (*Tiaroga cobitis*) (Region 2).

Progress in Revising the Lists

As described in section 4(b)(3)(B)(iii) of the Act, in order for us to make a ''warranted but precluded'' finding on a petitioned action, we must be making expeditious progress to add qualified taxa to the Lists of Endangered and Threatened Wildlife and Plants and to remove from the list taxa for which the protections of the Act are no longer necessary.

We are making expeditions progress in listing and delisting taxa during fiscal year 2000 (October 1, 1999, to October 1, 2000) as represented by our publication in the **Federal Register** of emergency rules for 1 taxa, final listing

actions for 38 species, proposed listing actions for 18 species, final delisting actions for 1 species, proposed delisting actions for 1 species, withdrawals of proposed rules for 1 species, final designation of critical habitat for 5 species, proposed designation of critical habitat for 17 species, 12-month petition finding for 7 species, and 90-day petition findings for 15 species.

Request for Information

We request you submit any further information on the taxa named in this notice as soon as possible or whenever it becomes available. Additionally, we invite any further comment or information on any candidate taxa mentioned in the October 25, 1999, Candidate Notice or Review or found on the Fish and Wildlife Service website. We especially seek information:

(1) indicating that we should remove a taxon from candidate or proposed status;

(2) indicating that we should add a taxon to the list of candidate taxa;

(3) recommending areas that we should designate as critical habitat for a taxon, or indicating that designation of critical habitat would not be prudent for a taxon;

(4) documenting threats to any of the included taxa;

(5) describing the immediacy or magnitude of threats facing candidate taxa;

(6) pointing out taxonomic or nomenclatural changes for any of the taxa;

(7) suggesting appropriate common names; or

(8) noting any mistakes, such as errors in the indicated historical ranges.

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Authority

This notice of review is published under the authority of the Endangered Species Act (16 U.S.C. 1531 *et seq.*).

Dated: December 8, 2000.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

TABLE 1.—PETITIONED CANDIDATES (ANIMAL AND PLANT)

[*denotes change in Listing Priority Number since October 25, 1999 review]

Status		Lead region	Scientific name	Family	Common name	Historic range
Category	Priority					
Mammals						
C	3	1	*Emballonura semicaudata.*	Emballonuridae	Bat, sheath-tailed (Aguijan, American Samoa population).	U.S.A. (AS, GU, MP (Aguijan)).
C	*2	1	*Spermophilus washingtoni.*	Sciuridae	Washington ground squirrel.	U.S.A. (OR, WA).
Removed	N/A	6	*Vulpes velox*	Canidae	Fox, swift (U.S. population).	U.S.A. (CO, IA, KS, MN, MT, ND, NE, NM, OK, SD, TX, WY), Canada.
Birds						
C	3	1	*Oceanodroma castro*	Hydrobatidae	Storm-petrel, band-rumped (=Harcourt's) (Hawaii population).	U.S.A. (HI).
C	8	2	*Tympanuchus pallidicinctus.*	Phasianidae	Lesser prairie chicken	U.S.A (CO, KS, NM, OK, TX).

TABLE 1.—PETITIONED CANDIDATES (ANIMAL AND PLANT)—Continued

[*denotes change in Listing Priority Number since October 25, 1999 review]

Status		Lead region	Scientific name	Family	Common name	Historic range
Category	Priority					
			Reptiles			
C	5	2	*Graptemys caglei*	Emydidae	Turtle, Cagle's map	U.S.A. (TX.)
			Amphibians			
C	5	1	*Ambystoma californiense.*	Ambystomatidae	Salamander, California tiger.	U.S.A. (CA).
C	*3	1	*Rana luteiventris* (formerly incl. In *R. pretiosa*).	Ranidae	Columbia spotted frog (Great Basis population).	U.S.A. (ID, NV, OR).
C	*2	1	*Rana pretoisa*	Ranidae	Frog, Oregon spotted (formerly spotted frog (W. Coast population)).	U.S.A. (CA, OR WA), Canada.
C	3	6	*Bufo boreas boreas*	Bufonidae	Toad, boreal (Southern Rocky Mtns. population).	U.S.A. (CO, MN, WY).
			Fish			
C	9	6	*Thymallus arcticus*	Salmonidae	Grayling, Arctic (Upper Missouri R. fluvial population).	U.S.A. (MT, WY).
C	2	2	*Gila intermedia*	Cyprinidae	Chub, Gila	U.S.A. (AZ, MN), Mexico.
C	2	6	*Macryhbopsis meeki*	Cyprinidae	Chub, sicklefin	U.S.A. (AR, IA, IL, KS, KY, LA, MO, MS, MT, NE, ND, SD, TN).
C	2	6	*Macryhbopsis gelida*	Cyrpinidae	Chub, sturgeon	U.S.A. (AR, IA, IL, KS, KY, LA, MO, MS, MT, NE, ND, SD, TN, WY).
			Snails			
C	8	2	*Pyrgulopsis (=Fontelicella) chupaderae.*	Hydrobiidae	Springsnail, Chupadera	U.S.A. (NM).
C	8	2	*Pyrgulopsis (=Fontelicella) gilae.*	Hydrobiidae	Springsnail, Gila	U.S.A. (NM).
C	2	2	*Tryonia kosteri*	Hydrobiidae	Snail, Koster's tyronia	U.S.A. (NM).
C	11	2	*Pyrgulopsis (=Fontelicella) thermalis.*	Hydrobiidae	Springsnail, New Mexico	U.S.A. (NM).
C	2	2	*Assiminea pecos*	Assununeidae	Pecos assiminea snail	U.S.A. (NM, TX, and Mexico).
C	2	2	*Pyrgulopsis (=Fontelicella) roswellensis.*	Hydrobiidae	Roswell springsnail	U.S.A. (NM).
			Insects			
C	9	6	*Cicindela limbata albissima.*	Cicindelidae	Coral Pink Sand Dunes tiger beetle.	U.S.A. (UT).
			Plants			
C	3	1	*Chorizanthe parryi* var. *fernandina.*	Polygonaceae	San Fernando Valley Spineflower.	

[FR Doc. 01–440 Filed 1–5–01; 8:45 am]

BILLING CODE 4310–55–U

Notices

Federal Register
Vol. 66, No. 5
Monday, January 8, 2001

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Public Information Collections Being Reviewed by the U.S. Agency for International Development; Comments Requested

SUMMARY: U.S. Agency for International Development (USAID) is making efforts to reduce the paperwork burden. USAID invites the general public and other Federal agencies to take this opportunity to comment on the following proposed and/or continuing information collections, as required by the Paperwork Reduction Act for 1995. Comments are requested concerning: (a) Whether the proposed or continuing collections 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 burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Submit comments on or before March 9, 2001.

FOR FURTHER INFORMATION CONTACT: Beverly Johnson, Bureau for Management, Office of Administrative Services, Information and Records Division, U.S. Agency for International Development, Room 2.07–106, RRB, Washington, DC 20523, (202) 712–1365 or via e-mail bjohnson@usaid.gov.

SUPPLEMENTARY INFORMATION:

OMB No: OMB 0412–0550.

Form No.: AID 1570–13 and 1570–14.

Title: Narrative/Time-Line and Report on Commodities (Quarterly Reports).

Type of Review: Renewal of Information Collection.

Purpose: The purpose of this information collection is to properly respond to the annual competition among applicants who apply on behalf of their sponsored overseas institutions, independent reviewers and ASHA need to assess the strength and capability of the U.S. organizations, the overseas institutions and the merits of their proposed projects. Easily accessible historical records on past accomplishments and performance by repeat USOs, would speed the grant making process and provide documented reasons for both successful and unsuccessful applications.

Annual Reporting Burden

Respondents: 70.

Total annual responses: 656.

Total annual hours requested: 1,824 hours.

Dated: December 28, 2000.

Joanne Paskar,

Chief, Information and Records Division, Office of Administrative Services, Bureau for Management.

[FR Doc. 01–401 Filed 1–5–01; 8:45 am]

BILLING CODE 6116–01–M

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Public Information Collection Requirements Submitted to OMB for Review

SUMMARY: U.S. Agency for International Development (USAID) has submitted the following information collections to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding this information collection are best assured of having their full effect if received within 30 days of this notification. Comments should be addressed to: Desk Officer for USAID, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington DC 20503. Copies of submission may be obtained by calling (202) 712–1365.

SUPPLEMENTARY INFORMATION:

OMB Number: OMB 0412–0012.

Form Number: AID 282.

Title: Supplier's Certificate Agreement with the U.S. Agency for International Development Invoice-and-Contract Abstract.

Type of Submission: Renewal of Information Collection.

Purpose: The U.S. Agency for International Development (USAID) finances goods and related services under its Commodity Import Program which are contracted for by public and private entities in the countries receiving the USAID assistance. Since USAID is not a party to these contracts, USAID needs some means to collect information directly from the suppliers of the goods and related services and to enable USAID to take an appropriate action against them in the event they do not comply with the applicable regulations. USAID does this by security from the suppliers, as a condition for the disbursement of funds a certificate and agreement with USAID which contains appropriate representations by the suppliers.

Annual Reporting Burden

Respondents: 400.

Total annual responses: 2,400.

Total annual hours requested: 1,200 hours.

Dated: December 28, 2000.

Joanne Paskar,

Chief, Information and Records Division, Office of Administrative Services, Bureau for Management.

[FR Doc. 01–402 Filed 1–5–01; 8:45 am]

BILLING CODE 6116–01–M

DEPARTMENT OF AGRICULTURE

Forest Service

Buck Springs Range Analysis EIS; Southwestern Region, Arizona, Coconino County, Coconino National Forests

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Coconino National Forest is planning to prepare an environmental impact statement on a proposal to manage livestock grazing use on the Buck Springs Range Allotment during the next 10 years.

DATES: Comments in response to this Notice of Intent concerning the scope of the analysis should be received in writing on or before February 7, 2001.

ADDRESSES: Send written comments to USDA Forest Service, Coconino National Forest, Blue Ridge Ranger Station, HC 31, Box 300, Happy Jack, AZ 86024. Electronic mail may be sent to cataylor01@fs.fed.us.

RESPONSIBLE OFFICIAL: The Forest Supervisor of the Coconino National Forest, Supervisor's Office 2323 E. Greenlaw Lane, Flagstaff AZ 86004, will decide what actions are most appropriate for managing the Buck Springs Range Allotment.

FOR FURTHER INFORMATION CONTACT: Cathy Taylor, Interdisciplinary Team Leader, Blue Ridge Ranger District, (520) 477–2255.

SUPPLEMENTARY INFORMATION: The proposal will issue a grazing permit for 634 cow/calf pairs and 8 horses. Annual Operating Plan would adjust the number of livestock allowed per year to resource conditions. The grazing strategy would be a deferred rotation system, with season of use running from about May 15 to October 15. Fencing, livestock trailing, water improvements, cattleguards, and riders would be used to manage the distribution of livestock and forage utilization, to avoid livestock grazing in some meadows and riparian areas, and to increase livestock control in sensitive areas. Approximately 22 miles of fence would be constructed, to split three pastures, exclude six meadows, and protect two springs. Dense thickets of small trees that currently impede the gathering of livestock would be precommercially thinned on 1500 acres to improve livestock movement, increase the understory diversity, reduce the risk of wildfire, and improve tree growth and vigor.

Preliminary issues include the effects of grazing on the environment, especially headwater meadows, and effects on species protected under the Endangered Species Act, specifically the Little Colorado spinedace and the Mexican spotted owl.

The environmental analysis process for the Buck Springs Range Allotment was initiated on June 25, 1998. An Interdisciplinary Team of Forest Service resource specialists, and representatives from the Arizona Game and Fish Department, US Fish and Wildlife Service, Arizona Department of Environmental Quality, and the allotment permittee, developed a guiding document for watershed recovery before undertaking an analysis of the allotment. They described the many factors affecting watershed conditions within the allotment, including elk and livestock grazing, recreation, transportation system, and introduced aquatic species. In a cooperative effort, the agencies making up the team developed the East Clear Creek Watershed Recovery Strategy for the Little Colorado Spinedace and Other Riparian Species to address many of those factors. Using the document to guide actions proposed for the Buck Springs Range Allotment, the Team developed objectives and proposed management practices for the allotment.

The resulting Proposed Action was mailed to 209 individuals, organizations and cooperating resource agencies for review and comment in April 1999. From comments received, the Team developed statements to capture the substantive issues and developed 6 additional alternatives other than the proposed action. If you commented during this scoping period, these comments are already incorporated into the analysis. Some of these alternatives differ in grazing strategies, utilization levels, permitted numbers of livestock, pastures utilized, and improvements required, and are briefly described as follows:

- Proposed action as discussed above.
- No graze for a 10-year period.
- Continue current grazing management (no action).
- Continue deferred rotation and rely heavily on herding to affect distribution of livestock and to protect sensitive riparian and headwater meadow habitats.
- Continue deferred rotation and emphasize the use of northern tier of pastures, with most southern pastures that include headwater meadows removed from the grazing land base.
- Implement a rest-rotation strategy, where one-half of the allotment is grazed each year. Distribution of livestock and use of sensitive drainages are addressed primarily through range improvements.
- Implement a rest-rotation strategy on the northern tier of pastures. Southern pastures with headwater meadows are removed from the grazing land base.

It is anticipated that environmental analysis and preparation of the draft and final environmental impact statements will take about six months. The Draft Environmental Impact Statement can be expected March of 2001 and the Final EIS in summer. The comment period on the draft environmental impact statement extends 45 days 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. To be the most helpful, comments on the draft environmental impact statement should be as specific as possible and may address the adequacy of the statement or the merits of the alternatives discussed (see Council of Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3).

In addition, Federal court decisions have established that 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 reviewers' position and contentions. *Vermont Yankee Nuclear Power Corp* v. *NRDC*, 435 US 519, 553 (1978). Environmental objections that could have been raised at the draft stage may be waived if not raised until after completion of the final environmental impact statement. *City of Angoon* v. *Hodel*, 9th Circuit, (1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). The reason for this is to ensure that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider 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.

Dated: December 18, 2000.

Jim Golden,

Forest Supervisor.

[FR Doc. 01–399 Filed 1–5–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Proposed Changes to Section 4 of the Iowa State Technical Guide

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture.

ACTION: Notice of availability of proposed changes in the Iowa NRCS

State Technical Guide for review and comment.

SUMMARY: It has been determined by the NRCS State Conservationist for Iowa that changes must be made in the NRCS State Technical Guide specifically in Section 4, Practice Standards and Specifications #590, Nutrient Management, to account for improved technology. This practice can be used in systems that treat highly erodible land.

DATES: Comments will be received on or before February 7, 2001.

FOR FURTHER INFORMATION CONTACT: Leroy Brown, State Conservationist, Natural Resources Conservation Service, Federal Building, 210 Walnut Street, 693 Federal Building, Des Moines, Iowa 50309; at 515/284–4260; fax 515/284–4394.

SUPPLEMENTARY INFORMATION: Section 343 of the Federal Agriculture Improvement and Reform Act of 1996 states that revisions made after enactment of the law to NRCS State technical guides used to carry out highly erodible land and wetland provisions of the law shall be made available for public review and comment. For the next 30 days the NRCS will receive comments relative to the proposed changes. Following that period a determination will be made by the NRCS regarding disposition of those comments and a final determination of change will be made.

Dated: December 26, 2000.

Dennis Pate,

Assistant State Conservationist-Technology.

[FR Doc. 01–400 Filed 1–5–01; 8:45 am]

BILLING CODE 3410–16–M

BROADCASTING BOARD OF GOVERNORS

Proposed Collection Reinstatement; Comment Request

SUMMARY: The Broadcasting Board of Governors (BBG), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on an information collection titled, ''Interviews and Other Audience Research for Radio and TV Marti''. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 [Public Law 104–13; 44 U.S.C. 3506(c)(2)(A)].

The information collection activity involved with this program is conducted pursuant to the mandate given to the BBG (formerly the United States Information Agency) in accordance with Public Law 98–11, the Radio Broadcasting to Cuba Act, dated, October 4, 1983, to provide for the broadcasting of accurate information to the people of Cuba and for other purposes. This act was then amended by Pub. Law 101–246, dated, February 16, 1990, which established the authority for TV Marti.

DATES: Comments are due on or before March 9, 2001.

FOR FURTHER INFORMATION CONTACT: The Agency Clearance Officer, Ms. Jeannette Giovetti, BBG, M/AO, Room 1657A–1, 330 Independence Avenue, SW., Washington, DC 20237, telephone (202) 205–9692, e-mail address JGiovett@IBB.GOV; or OMB Desk Officer for BBG, Mr. David Rostker, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10202, NEOB, Washington, DC 20503, Telephone (202) 395–3897.

Copies: Copies of the Request for Clearance (OMB 83–I), supporting statement, and other documents that will be submitted to OMB for approval may be obtained from the BBG Clearance Officer.

SUPPLEMENTARY INFORMATION: Public reporting burden for this proposed collection of information is estimated to average .11 hours per response (6.6 minutes), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Responses are voluntary and respondents will be required to respond only one time. Comments are requested on the proposed information collection concerning:

(a) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information has practical utility;

(b) The accuracy of the Agency's burden estimates;

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

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

Send comments regarding this burden estimate or any other aspect of this collection of information to the Agency Clearance Officer, Ms. Jeannette Giovetti, BBG, M/AO, Room 1657A–1, 330 Independence Avenue, SW., Washington, DC 20237, telephone (202) 205–9692, e-mail address JGiovett@IBB.GOV; or to the OMB Desk Officer for BBG, Mr. David Rostker, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10202, NEOB, Washington, DC 20503, Telephone (202) 395–3897.

Current Actions: The BBG is requesting reinstatement of this collection for a three-year period and approval for a revision to the burden hours.

Title: Interviews and Other Audience Research for Radio and TV Marti.

Abstract: Data from this information collection are used by BBG's Office of Cuba Broadcasting (OCB) in fulfillment of its mandate to evaluate effectiveness of Radio and TV Marti operations by estimating the audience size and composition for broadcasts; and assess signal reception, credibility and relevance of programming through this research.

Proposed Frequency of Responses:
Number of Respondents—4880.
Recordkeeping Hours—.11.
Total Annual Burden—560.

Dated: January 2, 2001.

Dennis D. Sokol,

Director of Administration.

[FR Doc. 01–450 Filed 1–5–01; 8:45 am]

BILLING CODE 8610–01–U

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–846]

Brake Rotors From the People's Republic of China: Preliminary Results and Partial Rescission of the Fourth New Shipper Review and Rescission of the Third Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results and partial rescission of fourth new shipper review and rescission of third antidumping duty administrative review.

SUMMARY: The Department of Commerce is currently conducting the fourth new shipper review and third administrative review of the antidumping duty order on brake rotors from the People's Republic of China covering the period April 1, 1999, through March 31, 2000. The fourth new shipper review covers two exporters. The Department of Commerce is preliminarily rescinding in part the fourth new shipper review with respect to one exporter. We have

preliminarily determined that sales have not been made below normal value by the other exporter. If these preliminary results are adopted in our final results of the fourth new shipper review, we will instruct the U.S. Customs Service to assess no antidumping duties on entries of subject merchandise during the period of review from the exporter that cooperated in the review, for which the importer-specific assessment rates are zero or *de minimis* (*i.e.*, less than 0.50 percent), and to continue to assess duties on all entries of subject merchandise made during the period of review by the other uncooperative exporter at the country-wide rate. Furthermore, we will instruct the U.S. Customs Service (''the Customs Service'') to require a cash deposit on all future entries of the subject merchandise from the uncooperative exporter at the country-wide rate.

The third administrative review covers three exporter/producer combinations (*see* ''Background'' section of this notice for further discussion). The Department of Commerce (''the Department'') is preliminarily rescinding the third administrative review because none of the respondents made shipments of the subject merchandise during the period of review (''POR''). Interested parties are invited to comment on these preliminary results. We will issue the final results no later than 120 days from the date of publication of this notice.

EFFECTIVE DATE: January 8, 2001.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Brian Ledgerwood, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–3836, respectively.

The Applicable Statute: Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (''the Act''), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR Part 351 (2000).

SUPPLEMENTARY INFORMATION:

Background

On April 28, 2000, the petitioner [1] requested an administrative review pursuant to 19 CFR 351.213(b) for three exporter/producer combinations that received zero rates in the less-than-fair-value (''LTFV'') investigation and thus were excluded from the antidumping duty order only with respect to brake rotors sold through the specified exporter/producer combinations.[2]

Also on April 28, 2000, the Department received timely requests from Hongfa Machinery (Dalian) Co., Ltd. (''Hongfa'') and Luoyang Haoxiang Brake Disc Factory (''Luoyang'') for a new shipper review of this antidumping duty order in accordance with 19 CFR 351.214(c). In their requests for a new shipper review and in accordance with 19 CFR 351.214(b)(2)(i) and (iii)(A), Hongfa and Luoyang each certified that it did not export the subject merchandise to the United States during the period covered by the original LTFV investigation, and that it is not affiliated with any company which exported subject merchandise to the United States during the period of investigation. Hongfa and Luoyang also certified that their export activities are not controlled by the central government of the People's Republic of China (''PRC''). Pursuant to 19 CFR 351.214(b)(2)(iv), Hongfa and Luoyang submitted documentation establishing the date on which the merchandise was first entered for consumption in the United States, the volume of that first shipment, and the date of the first sale to an unaffiliated customer in the United States.

On May 22, 2000, the excluded exporter/producer combinations submitted a letter in which they contended that the Department did not have the basis for conducting an administrative review of them because they were excluded from the antidumping duty order on brake rotors from the PRC. On May 26, 2000, the Department initiated an administrative review covering the exporter/producer combinations which received zero rates in the LTFV investigation only with respect to their U.S. sales of brake rotors produced by companies other than those included in the excluded exporter/producer combinations noted above (*see Initiation of Antidumping and Countervailing Duty Administrative Reviews* (65 FR 35320, June 2, 2000)). In accordance with 19 CFR 351.214(d), the Department also initiated a new shipper review covering Hongfa and Luoyang on May 26, 2000. *See Brake Rotors from the People's Republic of China: Initiation of New Shipper Antidumping Duty Review,* 65 FR 35322 (June 2, 2000).

On June 5 and 6, 2000, we issued a questionnaire to each PRC company listed in the brake rotor initiation notices. On June 28, 2000, the Department provided the parties an opportunity to submit publicly available information for consideration in these preliminary results. On June 29, 2000, Hongfa and Luoyang requested an extension of time until July 21, 2000, to file their responses to the antidumping duty questionnaire, which the Department subsequently granted on July 7, 2000.

Also on June 29, 2000, both respondents agreed to waive the time limits applicable to the new shipper review and to permit the Department to conduct the new shipper review concurrently with the administrative review. Therefore, the Department issued a **Federal Register** notice stating that it intended to conduct the new shipper review concurrent with the administrative review (*see Brake Rotors from the People's Republic of China: Notice of Extension of Time Limits for the Preliminary and Final Results of the Fourth New Shipper Antidumping Duty Review,* 65 FR 51294 (August 23, 2000)).

On July 7, 2000, each of the exporters which received zero rates in the LTFV investigation stated that during the POR it did not make U.S. sales of brake rotors produced by companies other than those included in its respective excluded exporter/producer combination. On July 21, 2000, Hongfa and Luoyang submitted their questionnaire responses. On July 26, 2000, the petitioner requested an extension of time until October 18, 2000, to submit publicly available information in this proceeding. On July 31, 2000, the Department granted the petitioner's request and extended the time limit for the submission of publicly available information by all parties.

On September 8, 2000, the petitioner submitted a letter in which it requested that the Department conduct verification of: (1) The responses submitted by the two respondents in the new shipper review; (2) the no-shipment claims made by the exporters named in the three exporter/producer combinations excluded from the antidumping duty order; and (3) the Ministry of Foreign Trade and Economic Cooperation (''MOFTEC'') and National Industrial and Commercial Administration Bureau (''NICAB''). On September 14, 2000, the Department

[1] The petitioner is the Coalition for the Preservation of American Brake Drum and Rotor Aftermarket Manufacturers.

[2] The excluded exporters/producer combinations are: (1) China National Automobile Industry Import & Export Corporation (''CAIEC'') or Shandong Laizhou CAPCO Industry (''Laizhou CAPCO'')/Laizhou CAPCO; (2) Shenyang Honbase Machinery Co., Ltd. (''Shenyang Honbase'') or Laizhou Luyuan Automobile Fittings Co., Ltd. (''Laizhou Luyuan'')/Shenyang Honbase or Laizhou Luyuan; and (3) China National Machinery and Equipment Import & Export (Xinjiang) Co., Ltd. (''Xinjiang'')/Zibo Botai Manufacturing Co., Ltd. (''Zibo'').

issued a decision memorandum which outlined the Department's reasons for conducting a review of the exporter/producer combinations receiving rates of zero in the LTFV investigation with respect to shipments of merchandise produced by manufacturers other than those in the respective excluded exporter/producer combinations (*see* September 14, 2000, Memorandum from the team to Louis Apple, Office Director). On September 15, 2000, the petitioner submitted comments on the questionnaire responses submitted by Hongfa and Luoyang. On September 25, 2000, the Department issued supplemental questionnaires to Hongfa and Luoyang. On September 29, 2000, Hongfa and Luoyang requested an extension of time until October 16, 2000, to file their responses to the supplemental questionnaire, which the Department subsequently granted on October 6, 2000.

In order to substantiate the claims made by the exporter/producer combinations excluded from the order that they did not ship merchandise from producers other than those covered by their exclusion, on September 27, 2000, the Department conducted a data query on brake rotor entries made during the POR from all exporters named in the excluded exporter/producer combinations. As a result of the data query on September 28, 2000, the Department requested that the Customs Service confirm the actual manufacturer for specific entries associated with the excluded exporter/producer combinations.

On October 4, 2000, in response to the petitioner's September 8, 2000, letter requesting the verification of all respondents in these reviews, the Department informed the petitioner that it (1) did intend to conduct verification of the responses submitted by Hongfa and Luoyang; (2) did not intend to conduct verification of the sales records of the exporters named in the three exporter/producer combinations unless the results of its Customs data query of U.S. entries of brake rotors during the POR revealed that an excluded exporter shipped brake rotors produced by a firm other than the producer named in the corresponding excluded exporter/producer combination; and (3) did not intend to visit MOFTEC or NICAB because the information provided by the petitioner in its September 8, 2000, submission did not serve as a sufficient basis for conducting such visits (*see* the October 4, 2000, Letter from Louis Apple, Office Director, to Mr. Leslie A. Glick for further details).

On October 16, 2000, the Department received a supplemental questionnaire response from Hongfa, but did not receive a response from Luoyang. On October 18, 2000, Luoyang's counsel submitted a letter which stated that it was withdrawing its notice of appearance on behalf of Luoyang in the proceeding. Also on October 18, 2000, the petitioner submitted publicly available information for use in valuing the factors of production. On October 25, 2000, the respondents provided rebuttal publicly available information and comments on the publicly available information submitted by the petitioner.

On October 20, 2000, the Department provided a verification outline to Hongfa. Also on October 20, 2000, the Department issued a letter to Luoyang which provided the firm with an additional extension of time to submit its supplemental questionnaire response. The Department also notified Luoyang that if it did not provide its supplemental questionnaire response by October 26, 2000, the Department would (1) conclude that Luoyang was no longer participating in the proceeding; (2) cancel plans to conduct verification of Luoyang's response; and (3) use the facts available with respect to Luoyang for the preliminary results.

On October 23, 2000, the petitioner submitted a letter objecting to the extension of time the Department had granted to Luoyang for its supplemental response. On October 24, 2000, the Department placed on the record correspondence obtained from the U.S. Embassy in Beijing which indicated that Luoyang did not intend to participate further in the new shipper review (*see* October 24, 2000, Memorandum from the case analyst to the file for further details). Also on October 24, 2000, the petitioner filed comments related to the Department's verification of Hongfa.

On October 25, 2000, the Department issued a memorandum stating that it preliminarily found no evidence that shipments of merchandise subject to the order were made by the three exporter/producer combinations during the POR. From October 30 through November 2, 2000, the Department conducted verification of the information submitted by Hongfa, in accordance with 19 CFR 351.307.

On November 15, 2000, the petitioner submitted a copy of a PRC law (*i.e.,* ''Rules for the Implementation of the Law of the People's Republic of China on Foreign-Capital Enterprises'')(''Rules for Foreign-Capital Enterprises'') and claimed that the Department should resort to facts available with respect to Hongfa because Hongfa did not provide a copy of this law in its entirety at verification and because certain sections of the law allegedly demonstrate that the PRC government maintains de jure and de facto control over foreign-capital companies like Hongfa in the PRC. Moreover, the petitioner renewed its request that the Department conduct verification of MOFTEC and other PRC government entities based on the contents of the PRC law it submitted.

On November 30, 2000, the Department issued its verification report on Hongfa.

Scope of Reviews

The products covered by these reviews are brake rotors made of gray cast iron, whether finished, semifinished, or unfinished, ranging in diameter from 8 to 16 inches (20.32 to 40.64 centimeters) and in weight from 8 to 45 pounds (3.63 to 20.41 kilograms). The size parameters (weight and dimension) of the brake rotors limit their use to the following types of motor vehicles: automobiles, all-terrain vehicles, vans and recreational vehicles under ''one ton and a half,'' and light trucks designated as ''one ton and a half.''

Finished brake rotors are those that are ready for sale and installation without any further operations. Semi-finished rotors are those on which the surface is not entirely smooth, and have undergone some drilling. Unfinished rotors are those which have undergone some grinding or turning.

These brake rotors are for motor vehicles, and do not contain in the casting a logo of an original equipment manufacturer (''OEM'') which produces vehicles sold in the United States (*e.g.,* General Motors, Ford, Chrysler, Honda, Toyota, Volvo). Brake rotors covered in these reviews are not certified by OEM producers of vehicles sold in the United States. The scope also includes composite brake rotors that are made of gray cast iron, which contain a steel plate, but otherwise meet the above criteria. Excluded from the scope of the reviews are brake rotors made of gray cast iron, whether finished, semifinished, or unfinished, with a diameter less than 8 inches or greater than 16 inches (less than 20.32 centimeters or greater than 40.64 centimeters) and a weight less than 8 pounds or greater than 45 pounds (less than 3.63 kilograms or greater than 20.41 kilograms).

Brake rotors are currently classifiable under subheading 8708.39.5010 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of these reviews is dispositive.

Period of Reviews

The period of review (''POR'') covers April 1, 1999, through March 31, 2000.

Verification

As provided in section 782(i)(2) of the Act, we verified information provided by Hongfa. We used standard verification procedures, including on-site inspection of the manufacturer's facilities and examination of relevant sales and financial records. Our verification results are outlined in the verification report (*see* the November 30, 2000, Hongfa verification report for further discussion).

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(3), we have preliminarily determined that, during the POR, the three exporter/producer combinations which received zero rates in the LTFV investigation did not make shipments of subject merchandise to the United States during the POR. Specifically, we preliminarily determined that during the POR, (1) neither CAIEC nor Laizhou CAPCO exported brake rotors to the United States that were manufactured by producers other than Laizhou CAPCO; (2) neither Shenyang Honbase nor Laizhou Luyuan exported brake rotors to the United States that were manufactured by producers other than Shenyang Honbase or Laizhou Luyuan; and (3) Xinjiang did not export brake rotors to the United States that were manufactured by producers other than Zibo (*see* October 25, 2000, Memorandum from the case analyst to the file). In order to make this determination, we first examined POR subject merchandise shipment data maintained by the Customs Service. We then requested the Customs Service to examine the documentation filed at the U.S. port for selected entries made by the exporters at issue to determine the manufacturer of the merchandise. Based on the results of our query, we are preliminarily rescinding the administrative review because we found no evidence that the exporter/producer combinations subject to this review made U.S. shipments of the subject merchandise during the POR.

Partial Rescission of New Shipper Review

We are also preliminarily rescinding in part the fourth new shipper review with respect to Luoyang based on its decision not to submit a response to the Department's supplemental questionnaire and not to cooperate in this review which Luoyang itself requested. As a consequence of Luoyang's decision to discontinue participation in this review, the Department canceled verification of Luoyang's questionnaire response, including its separate rate information. Therefore, we consider Luoyang to be an uncooperative respondent and have made the adverse inference that Luoyang does not qualify for a separate rate. We, therefore, have treated Luoyang as part of the non-market economy (''NME'') entity. As part of the NME entity, Luoyang is not entitled to a rate as a new shipper, because the NME entity as a whole was subject to the LTFV investigation. For these reasons, we are rescinding the new shipper review with respect to Luoyang.

Separate Rates

In proceedings involving NME countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and thus should be assessed a single antidumping duty deposit rate (*i.e.,* a PRC-wide rate).

The cooperative respondent in the new shipper review, Hongfa, is wholly foreign-owned. Thus, for Hongfa, because we have no evidence indicating that it is under the control of the PRC government, a separate rates analysis is not necessary to determine whether it is independent from government control (*see Notice of Final Determination of Sales at Less Than Fair Value: Creatine Monohydrate from the People's Republic of China,* 64 FR 71104, 71105 (December 20, 1999); *Preliminary Results of First New Shipper Review and First Antidumping Duty Administrative Review: Certain Preserved Mushrooms from the People's Republic of China,* 65 FR 66703, 66705 (November 7, 2000); and *Notice of Final Determination of Sales at Less Than Fair Value: Bicycles From the People's Republic of China* (''*Bicycles*'') 61 FR 19026 (April 30, 1996)).

With respect to the petitioner's November 15, 2000, claim that Hongfa should be denied a separate rate because it withheld information at verification, we find that Hongfa complied fully with the Department's request for information. Specifically, the Department requested Hongfa to provide documentation on the registered capital requirements for wholly-foreign owned companies in the PRC. In response to the Department's request for information, Hongfa provided an excerpt from the PRC law, Rules for Foreign-Capital Enterprises, which discussed the timeframe PRC companies (such as Hongfa) had in order to meet registered capital requirements for obtaining business licenses (*see* page five of the Hongfa verification report). Hongfa complied fully with the Department's request for information in this area. Thus, the petitioner's claim is without merit.

With respect to the petitioner's claim that certain sections of the PRC government document at issue indicate *de jure* and *de facto* government control of the export activities of wholly foreign-owned companies such as Hongfa, we note that the document in question does not contain compelling information which would lead us to believe that the PRC government exercises *de jure* or *de facto* control over all foreign-owned PRC companies. (For further discussion, see the control criteria of our separate rates test arising out of the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) and amplified in the *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*'').) In Hongfa's case, since this company is wholly foreign-owned, it is not necessary to apply the separate rates test to it (*see* discussion above). Therefore, the petitioner's claim that certain sections of the 1990 Rules for Foreign-Capital Enterprises indicate *de jure* and *de facto* government control is moot.

Finally with respect to the petitioner's request that the Department should conduct visits of MOFTEC and NICAB based on the requirements contained in the Rules for Foreign Enterprises, the Department does not consider the contents of that law to provide sufficient grounds for conducting visits at MOFTEC and NICAB in order to further interpret the regulations contained in the above-mentioned document.

Fair Value Comparisons

To determine whether sales of the subject merchandise by Hongfa to the United States were made at LTFV, we compared the export price to the normal value, as described in the ''Export Price'' and ''Normal Value'' sections of this notice, below.

Export Price

We used export price methodology in accordance with section 772(a) of the Act because the subject merchandise was sold by the exporter directly to an unaffiliated customer in the United States prior to importation and constructed export price was not otherwise indicated.

For Hongfa, we calculated export price based on packed, FOB foreign port prices to the first unaffiliated purchaser in the United States. Where appropriate,

we made deductions from the starting price (gross unit price) for foreign inland freight and foreign brokerage and handling charges in the PRC, in accordance with section 772(c) of the Act. Because foreign inland freight and foreign brokerage and handling fees were provided by PRC service providers or paid for in a reminbi, we based those charges on surrogate rates from India (*see* ''Surrogate Country'' section below for further discussion of our surrogate country selection). To value foreign inland trucking charges, we used a November 1999 average truck freight value based on price quotes from Indian trucking companies. We most recently used this rate in the second administrative review of brake rotors from the PRC (*see Brake Rotors from the People's Republic of China: Final Results of Third New Shipper Review and Final Results and Partial Rescission of Second Antidumping Duty Administrative Review*, 65 FR 64664 (October 30, 2000) (which cites to the ''Issues and Decision Memorandum'' from Richard W. Moreland, Deputy Assistant Secretary for Import Administration, to Troy H. Cribb, Assistant Secretary for Import Administration, dated October 24, 2000)) (''*Brake Rotors Second Administrative Review*'')). To value foreign brokerage and handling expenses, we relied on public information reported in the 1997–1998 antidumping duty new shipper review of stainless steel wire rod from India (*see* also *Brake Rotors Second Administrative Review*). Based on our verification findings, we revised the reported distance from Hongfa to the port of exportation (*see* Hongfa verification report at page 3).

In its pre-verification comments, the petitioner claimed that Hongfa's POR sale is not a *bona fide* transaction due to the circumstances surrounding the sale. In prior cases, the Department has considered factors such as timing, sale price, transportation costs, other expenses borne by the importer, and whether the merchandise was resold by the importer at a loss to determine whether a sale was a *bona fide* transaction (*see Preliminary Results of First New Shipper Review and First Antidumping Duty Administrative Review: Certain Preserved Mushrooms from the People's Republic of China*, 65 FR 66703, 66706 (November 7, 2000)) (''*Mushrooms from the PRC''). (See also Certain Cut-to-Length Carbon Steel Plate from Romania: Notice of Rescission of Antidumping Duty Administrative Review*, 63 FR 47232 (September 4, 1998) and *American Silicon Technologies* v. *United States*, CIT Slip Op. 00–84 (July 17, 2000).) As described in the Hongfa verification report, we verified that Hongfa made only one sale to the U.S. market during the POR and that Hongfa has made no other sales to the United States since the POR (*i.e.,* as of the date of verification). Therefore, unlike *Mushrooms from the PRC,* we could not compare sales prices for the subject merchandise during the POR with sales prices after the POR. Moreover, we have no evidence on the record to support a conclusion that the price for the reviewed sale is not commercially reasonable or the result of arm's-length bargaining. There is also no record evidence that the importer resold the merchandise at a loss. Furthermore, the transportation costs and other expenses borne by the importer based on the respondent's terms of sale are consistent with those incurred by other importers of the subject merchandise in previous administrative reviews, new shipper reviews and the LTFV investigation. In addition, while the sale occurred shortly before the end of the POR, the timing of the transaction is not a basis in-and-of-itself to render the transaction less than *bona fide* (*see Mushrooms from the PRC,* 65 at FR 66706). Therefore, absent evidence to the contrary, we have determined Hongfa's sale to be a *bona fide* transaction for purposes of this review.

Normal Value

A. Non-Market Economy Status

In every case conducted by the Department involving the PRC, the PRC has been treated as a NME country. Pursuant to section 771(18)(C)(i) of the Act, any determination that a foreign country is a NME country shall remain in effect until revoked by the administering authority (*see Notice of Preliminary Results of Antidumping Duty Administrative Review and New Shipper Reviews, Partial Rescission of the Antidumping Duty Administrative Review, and Rescission of a New Shipper Review: Freshwater Crawfish Tail Meat From the People's Republic of China*, 65 FR 60399, 60404 (October 11, 2000). None of the parties to this proceeding has contested such treatment. Accordingly, we calculated normal value in accordance with section 773(c) of the Act, which applies to NME countries.

B. Surrogate Country

Section 773(c)(4) of the Act requires the Department to value a NME producer's factors of production, to the extent possible, in one or more market economy countries that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. India and Indonesia are among the countries comparable to the PRC in terms of overall economic development (*see* June 12, 2000, Memorandum from the Office of Policy to the case analyst). In addition, based on publicly available information placed on the record, India is a significant producer of the subject merchandise. Accordingly, we considered India the primary surrogate country for purposes of valuing the factors of production because it meets the Department's criteria for surrogate country selection. Where we could not find surrogate values from India, we used values from Indonesia.

C. Factors of Production

In accordance with section 773(c) of the Act, we calculated normal value based on the factors of production which included, but were not limited to: (A) hours of labor required; (B) quantities of raw materials employed; (C) amounts of energy and other utilities consumed; and (D) representative capital costs, including depreciation. We used the factors reported by Hongfa which produced the brake rotors it exported to the United States during the POR. To calculate normal value, we multiplied the reported unit factor quantities by publicly available Indian or Indonesian values. Based on our verification findings, we revised (1) the factor for lug bolts; (2) the factor for packing labor; and (3) the distances from Hongfa to each of its suppliers (*see* page three of the Hongfa verification report and December 18, 2000, Memorandum from case analyst to the file).

In its October 18, 2000, publicly available information submission, the petitioner argued that the Department should use price data from International Business Information Services (''IBIS'') rather than from the Indian government publication *Monthly Statistics of the Foreign Trade of India (''Monthly Statistics'')* to value a number of direct and packing material inputs because the IBIS data is (1) the most contemporaneous with the POR; (2) it is based on Indian Customs statistics; and (3) it has been used to value inputs in previous NME cases. In its October 25, 2000, rebuttal comments, the respondent pointed out that the IBIS data, though more contemporaneous to the POR than *Monthly Statistics*, is less representative of the import prices paid for the inputs in question because the values the petitioner submitted from IBIS either were based on specific

shipments from only a few market economy countries or the values were not specific to the input reported by the respondent. After considering the data and arguments made by the parties with respect to this issue, for these preliminary results, we have relied on data from *Monthly Statistics* rather than IBIS to value the inputs in question because either the former data were more representative of Indian import prices or the latter data did not allow the Department to value properly the factor reported by the respondent (*see* detailed discussion below).

The Department's selection of the surrogate values applied in this determination was based on the quality, specificity, and contemporaneity of the data. As appropriate, we adjusted input prices to make them delivered prices. For those values not contemporaneous with the POR and quoted in a foreign currency, we adjusted for inflation using wholesale price indices published in the International Monetary Fund's *International Financial Statistics.*

To value pig iron, ferrosilicon, and ferromanganese, we used April 1998-December 1998 average import values from *Monthly Statistics.* For steel scrap and lubrication oil, we used April 1998-August 1998 average import values from *Monthly Statistics.* For limestone, we used an April 1998–March 1999 average import value from *Monthly Statistics* rather than the May 1999–March 2000 IBIS value. *Monthly Statistics* provided a more representative Indian import value for limestone because it covers all imports of limestone into India. The IBIS data appears to be based on a limited number of shipments of limestone to India. Furthermore, one of those limestone shipments is from an unknown exporting country accounting for 51 percent of the total import value based on the IBIS data.

The brake rotors Hongfa produced during the POR use lug bolts and ball bearing cups. Because we could not obtain a product-specific price from India to value lug bolts (*see Bicycles,* 61 FR at 19040 (Comment 17)), we used a January-March 1999 product-specific import value from the Indonesian government publication *Foreign Trade Statistical Bulletin.* To value ball bearing cups, we used an April 1998-December 1998 average import value from *Monthly Statistics.*

To value coking coal, we used an April 1998-August 1998 average import price from *Monthly Statistics.* We also added an amount for loading and additional transportation charges associated with delivering coal to the factory based on June 1999 Indian price data contained in the periodical *Business Line.* To value firewood, we used a 1991 domestic value from the Food and Agricultural Organization of the United Nations' working paper, *Wood Materials from Non-Forest Areas,* which is the most recent value available for this input. To value electricity, we used data from the Indian publications *1995 Conference of Indian Industries: Handbook of Statistics* and *The Center for Monitoring Indian Economy* and the methodology used in two recent NME cases. (*See Persulfates from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Partial Rescission of Administrative Review,* 65 FR 46691, 46692 (July 31, 2000); *Manganese Metal from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 65 FR 30067, 30068 (May 10, 2000); and Preliminary Results Valuation Memorandum).

We valued labor based on a regression-based wage rate, in accordance with 19 CFR 351.408(c)(3).

To value selling, general, and administrative (''SG&A'') expenses, factory overhead and profit, we used the 1998 financial data of Jayaswals Neco Limited and the 1998–1999 financial data of Kalyani Brakes Limited (''Kalyani'') and Rico Auto Industries Limited (''Rico'').

Where appropriate, we removed from the surrogate overhead and SG&A calculations the excise duty amount listed in the financial reports (*see Brake Rotors Investigation,* 62 FR at 9164). We made certain adjustments to the ratios calculated as a result of reclassifying certain expenses contained in the financial reports. In utilizing the financial data of the Indian companies, we treated the line item labeled ''stores and spares consumed'' as part of factory overhead because stores and spares are not direct materials consumed in the production process. Based on publicly available information, we considered the molding materials (*i.e.,* sand, bentonite, coal powder, steel pellets, lead powder, and waste oil) to be indirect materials included in the ''stores and spares consumed'' category of the financial statements. We based our factory overhead calculation on the cost of manufacturing. We also included interest and/or financial expenses in the SG&A calculation. In addition, we only reduced interest and financial expenses by amounts for interest income if the Indian financial report noted that the income was short-term in nature. Where a company did not distinguish interest income as a line item within total ''other income,'' we used the ratio of interest income to total other income as reported for the Indian metals industry in the *Reserve Bank of India Bulletin* to calculate the interest income amount. For example, if an Indian company's financial statement indicated that the company had miscellaneous receipts or other income under the general category ''other income,'' we applied a ratio (based on data contained in *Reserve Bank of India Bulletin*) to that miscellaneous receipts or other income figure in the financial statement to determine the amount associated with short-term interest income. To avoid double-counting, we treated the line item ''packing, freight, and delivery charges'' as expenses to be valued separately. Specifically, to determine the packing expense, we used Hongfa's reported packing material factors. We used the corrected distance (per verification findings) to determine the foreign inland freight expense (*see* page three of the Hongfa verification report for further discussion). For a further discussion of other adjustments made, *see* the Preliminary Results Valuation Memorandum.

All inputs were shipped by truck. Therefore, to value PRC inland freight, we used a November 1999 average truck freight value based on price quotes from Indian trucking companies.

In accordance with the decision of the Court of Appeals for the Federal Circuit in *Sigma Corp.* v. *United States,* 117 F. 3d 1401 (1997), we revised our methodology for calculating source-to-factory surrogate freight for those material inputs that are valued based on CIF import values in the surrogate country. Therefore, we have added to CIF surrogate values from India a surrogate freight cost using the shorter of the reported distances from either the closest PRC port of importation to the factory, or from the domestic supplier to the factory on an input-specific basis.

To value corrugated cartons and steel strip, we used April 1998–December 1998 average import values from *Monthly Statistics.* For plastic bags, we used an April 1997–March 1998 average import value for plastic bags from *Monthly Statistics* because that data (which was based on plastic bag imports from 18 market economy countries) was a more representative Indian import value for plastic bags than the more contemporaneous IBIS data (which was based on one shipment from one country). To value adhesive tape and nails, we used April 1998–March 1999 average import values from *Monthly Statistics* because the data (which was based on imports of adhesive tape from 26 market economy countries and imports of nails from 10 market economy countries) was also more representative of Indian import prices

for tape and nails than the more contemporaneous IBIS data (which was based on one shipment of tape and 12 shipments of nails from one country). To value pallet wood, we used an April 1995–March 1996 import value per kilogram from *Monthly Statistics* rather than values obtained after March 1996, because the more contemporaneous values appeared aberrational relative to the overall value of the subject merchandise (*see Brake Rotors Second Administrative Review*). Moreover, we used the value per kilogram from *Monthly Statistics* rather than the more contemporaneous value per piece from IBIS because the value from IBIS did not indicate the size or weight of a piece of wood in a manner which would have allowed the Department to value the factor reported by the respondent.

Preliminary Results of the Review

We preliminarily determine that the following margin exists for Hongfa during the period April 1, 1999, through March 31, 2000:

Manufacturer/producer/exporter	Margin percent
Hongfa Machinery (Dalian) Co., Ltd.	0.00

We will disclose the calculations used in our analysis to parties to this proceeding within five days of the date of publication of this notice. Any interested party may request a hearing within 30 days of publication of this notice. Any hearing, if requested, will be held on January 31, 2001.

Interested parties who wish to request a hearing or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, Room B–099, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *See* 19 CFR 351.310(c).

Issues raised in the hearing will be limited to those raised in case briefs and rebuttal briefs. Case briefs from interested parties may be submitted not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, will be due not later 37 days after the date of publication of this notice. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument (1) a statement of the issue and (2) a brief summary of the argument. Parties are also encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited.

The Department will issue the final results of these administrative and new shipper reviews, including the results of its analysis of issues raised in any such written briefs or at the hearing, if held, not later than 120 days after the date of publication of this notice.

Assessment Rates

The Department shall determine, and Customs shall assess, antidumping duties on all appropriate entries. Pursuant to 19 CFR 351.212(b)(1), we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of the dumping margins calculated for the examined sales to the total entered value of those same sales. In order to estimate the entered value, we will subtract applicable movement expenses from the gross sales value. In accordance with 19 CFR 351.106(c)(2), we will instruct Customs to liquidate without regard to antidumping duties all entries of subject merchandise during the POR for which the importer-specific assessment rate is zero or *de minimis* (*i.e.,* less than 0.50 percent). For entries subject to the PRC-wide rate, Customs shall assess *ad valorem* duties at the rate established in the LTFV investigation. The Department will issue appropriate appraisement instructions directly to Customs upon completion of this review.

Cash Deposit Requirements

Upon completion of this new shipper review, for entries from Hongfa, we will require cash deposits at the rate established in the final results pursuant to 19 CFR 351.214(e) and as further described below.

The following deposit requirements will be effective upon publication of the final results of these administrative and new shipper antidumping duty administrative reviews for all shipments of brake rotors from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for Hongfa will be the rate established in the final results; (2) the cash deposit rate for PRC exporters who received a separate rate in a prior segment of the proceeding will continue to be the rate assigned in that segment of the proceeding; (3) the cash deposit rate for the PRC NME entity (including Luoyang) will continue to be 43.32 percent; and (4) the cash deposit rate for non-PRC exporters of subject merchandise from the PRC will be the rate applicable to the PRC supplier of that exporter. These requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) 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 the subsequent assessment of double antidumping duties.

These administrative and new shipper administrative reviews and notice are in accordance with section 751(a)(1) and (2)(B) of the Act (19 U.S.C. 1675(a)(1) and (2)(B)) and 19 CFR 351.213 and 351.214.

Dated: January 2, 2001.

Troy H. Cribb,

Assistant Secretary for Import Administration.

[FR Doc. 01–457 Filed 1–5–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–817]

Oil Country Tubular Goods from Mexico: Extension of Time Limit for Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 8, 2001.

FOR FURTHER INFORMATION CONTACT: Phyllis Hall at (202) 482–1398 or Dena Aliadinov at (202) 482–2667, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Statutory Time Limits

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department of Commerce (''the Department'') to make a preliminary determination within 245 days after the last day of the anniversary month of an order for which a review is requested, and a final determination within 120 days after the date on which the preliminary determination is published. However, if it is not

practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary determination to a maximum of 365 days and for the final determination to 180 days (or 300 days if the Department does not extend the time limit for the preliminary determination) from the date of publication of the preliminary determination.

Background

On August 31,1999, Tubos de Acero de Mexico, S.A. de C.V. (''TAMSA'') and Hylsa S.A. de C.V. (''Hylsa'') requested that the Department conduct an administrative review of the antidumping duty order on oil country tubular goods (''OCTG'') from Mexico. The Department initiated this review on September 24, 1999. See 64 FR 53318 (October 1, 1999). On September 12, 2000, the Department published the preliminary results of the review in the **Federal Register** (65 FR 54998). The final results are due no later than January 10, 2001.

Extension of Time Limit for Preliminary Results of Review

We determine that it is not practicable to complete the final results of this review within the original time limits mandated by section 751 (a)(3)(A) of the Act. The Department is therefore extending the time limit for completion of the final results until no later than March 12, 2001. See Decision Memorandum from Richard Weible to Joseph A. Spetrini, dated December 29, 2000, which is on file in the Central Records Unit, Room B–099 of the main Commerce building.

This extension of the time limit is in accordance with section 751 (a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: December 29, 2000.

Joseph A. Spetrini,

Deputy Assistant Secretary, Enforcement Group III.

[FR Doc. 01–453 Filed 1–5–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–824]

Notice of Extension of the Time Limit for Preliminary Results of Antidumping Duty Administrative Review: Stainless Steel Sheet and Strip in Coils From Italy

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 8, 2001.

FOR FURTHER INFORMATION CONTACT: Carrie Blozy, AD/CVD Enforcement Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0165.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act) are to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce's (the Department's) regulations are to 19 CFR part 351 (2000).

Background

On October 30, 2000, the Department published a notice of initiation of the administrative review of the antidumping duty order on Stainless Steel Sheet and Strip in Coils from Italy, covering the period January 4, 1999 through June 30, 2000 (65 FR 64662). The preliminary results are currently due no later than April 2, 2001.

Extension of Time Limit for Preliminary Results

Because of the complex issues enumerated in the Memorandum from Edward C. Yang to Joseph A. Spetrini, *Extension of Time Limit for the Preliminary Results of Administrative Review of Certain Stainless Steel Sheet and Strip in Coils from Italy*, dated January 2, 2001, and on file in the Central Records Unit (CRU) of the Main Commerce Building, Room B–099, we find that it is not practicable to complete this review by the scheduled deadline. Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time period for issuing the preliminary results of review by 90 days (*i.e.*, until July 2, 2001).

Dated: January 2, 2001.

Joseph A. Spetrini,

Deputy Assistant Secretary, AD/CVD Enforcement Group III.

[FR Doc. 01–452 Filed 1–5–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of Rochester; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. Law 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 00–034. *Applicant:* University of Rochester, Rochester, NY 14623. *Instrument:* Scanning Nearfield Optical Microscope. *Manufacturer:* WITec, Germany. *Intended Use:* See notice at 65 FR 65296, November 1, 2000.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides: (1) an atomic force microscope with a metal probe operating in a vertical displacement AC mode and (2) simultaneous scanning atomic-force and near-field-optical microscopy on identical sample zones maintaining sample registration with nanometer accuracy. The National Institute of Standards and Technology advised December 21, 2000 that (1) these capabilities are pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 01–454 Filed 1–5–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of Wisconsin-Madison; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. Law 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 00–036. *Applicant:* University of Wisconsin-Madison, Madison, WI 53706. *Instrument:* Telecommunications Instrumentation Modeling System, Model TIMS–301. *Manufacturer:* Emona Instruments Pty Ltd., Australia. *Intended Use:* See notice at 65 FR 68981, November 15, 2000.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides expandable and customizable rack-mounted student workstations for laboratory instruction of optical and RF-based telecommunication techniques with 49 basic and advanced project modules currently available. A university department of electrical engineering advised December 21, 2000 that (1) these capabilities are pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 01–455 Filed 1–5–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Washington University School of Medicine; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. Law 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 00–037. *Applicant:* Washington University School of Medicine, St. Louis, MO 63110. *Instrument:* Flash Lamp System with Accessories. *Manufacturer:* Rapp OptoElectronic, Germany. *Intended Use:* See notice at 65 FR 70549, November 24, 2000.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides special filters for applications using caged Ca^{2+} compounds with an energy density of 400 mJ/cm^2 in the UV. The National Institutes of Health advises in its memorandum of December 5, 2000 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 01–456 Filed 1–5–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF DEFENSE

National Reconnaissance Office; Privacy Act of 1974; System of Records

AGENCY: National Reconnaissance Office, DOD.

ACTION: Notice to add a system of records.

SUMMARY: The National Reconnaissance Office is adding a system of records notice to its inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on February 7, 2001, unless comments are received which result in a contrary determination.

ADDRESSES: National Reconnaissance Office, 14675 Lee Road Chantilly, VA 20151–1715.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Freimann at (703) 808–5029.

SUPPLEMENTARY INFORMATION: The National Reconnaissance Office systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on December 20, 2000, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: December 21, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

NRO–23

SYSTEM NAME:

Counterintelligence Issue Files.

SYSTEM LOCATION:

Office of Counterintelligence, National Reconnaissance Office, 14675 Lee Road, Chantilly, VA 20151–1715.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

National Reconnaissance Office civilian, military, and contractor personnel who have had foreign travel contacts, incidents, or concerns, and any persons relating to a counterintelligence concern, incident or inquiry, as well as the points of contact.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, organization, company, date and place of birth, country, action officer, date received, point of contact, and status of the case including investigatory materials and files.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 424; National Security Act of 1947, as amended, 50 U.S.C. 401 *et seq.*; E.O. 12333; E.O. 12958; E.O. 12968; and E.O. 9397 (SSN).

PURPOSE(S):

Information is used to assign, categorize and administratively track foreign travel, contacts, and incidents or

concerns; monitor, analyze, and track counterintelligence activities; and prepare and pursue investigations involving counterintelligence activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routines Uses' published at the beginning of the NRO compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper files and on automated information systems.

RETRIEVABILITY:

Name, Social Security Number, organization, company, country, date received, action officer, point of contact and case status.

SAFEGUARDS:

Records are stored in a secure, gated facility, guard, badge, and password access protected. Access to and use of these records are limited to the Counterintelligence staff whose official duties require such access. Electronic data is stored on a networked (Local Area Network) PC, password restricted to the use of the Counterintelligence Staff.

RETENTION AND DISPOSAL:

Records are permanent.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Counterintelligence, National Reconnaissance Office, 14675 Lee Road, Chantilly, VA 20151–1715.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the National Reconnaissance Office, Information Access and Release Center, 14675 Lee Road, Chantilly, VA 20151–1715.

Request should include the individual's full name and any aliases or nicknames, address, Social Security Number, current citizenship status, date and place of birth.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed without the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

RECORD ACCESS PROCEDURES:

Individuals seeking to access information about themselves contained in this system should address written inquiries to the National Reconnaissance Office, Information Access and Release Center, 14675 Lee Road, Chantilly, VA 20151–1715.

Request should include the individual's full name, and any aliases or nicknames, address, Social Security Number, current citizenship status, date and place of birth.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed without the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

CONTESTING RECORD PROCEDURES:

The NRO rules for accessing records, for contesting contents and appealing initial agency determinations are published in NRO Directive 110–3 and NRO Instruction 110–5; 32 CFR part 326; or may be obtained from the Privacy Act Coordinator, National Reconnaissance Office, 14675 Lee Road, Chantilly, VA 20151–1715.

RECORD SOURCE CATEGORIES:

Information is supplied by the individual, by parties other than the individual, and by government agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Investigatory material compiled for law enforcement purposes may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of such information, the individual will be provided access to such information except to the extent that disclosure would reveal the identity of a confidential source.

Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

An exemption rule for this exemption has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 32 CFR part 505. For additional information contact the system manager.

[FR Doc. 01–415 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–U

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DOD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Army is proposing to alter a system of records notice to its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended. The alteration expands the categories of individuals covered to include any individual on any DoD base or installation whose privately owned animal receives veterinary care. Previously, the system of records covered only those individuals whose animals were treated on Army installations and activities.

DATES: This proposed action will be effective without further notice on February 7, 2001 unless comments are received which result in a contrary determination.

ADDRESSES: Records Management Division, U.S. Army Records Management and Declassification Agency, ATTN: TAPC–PDD–RP, Stop 5603, Ft. Belvoir, VA 22060–5603.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Thornton at (703) 806–4390 or DSN 656–4390 or Ms. Christie King at (703) 806–3711 or DSN 656–3711.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of

records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on December 19, 2000, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: December 20, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0040–905 DASG

SYSTEM NAME:

Privately Owned Animal Record Files (August 7, 1997, 62 FR 24534).

CHANGES:

* * * * *

SYSTEM NAME:

Add 'Defense' to beginning of entry.

SYSTEM LOCATION:

Delete entry and replace with 'Medical facilities on DoD bases and installations where veterinary services are provided.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Persons who privately own animals which receive veterinary care on any DoD base or installation.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Add to entry 'DoD Directive 6015.5, Joint Use of Military Health and Medical Facilities and Service; and Army Regulation 40–905, Veterinary Health Services.'

* * * * *

STORAGE:

Delete entry and replace with 'Paper records in file folders and electronic storage media.'

* * * * *

A0040–905 DASG

SYSTEM NAME:

Defense Privately Owned Animal Record Files.

SYSTEM LOCATION:

Medical facilities on DoD bases and installations where veterinary services are provided.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons who privately own animals which receive veterinary care on any DoD base or installation.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, home address and telephone number of animal's owner; record of treatment of animal; and related information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army; DoD Directive 6015.5, Joint Use of Military Health and Medical Facilities and Service; Army Regulation 40–905, Veterinary Health Services; and E.O. 9397 (SSN).

PURPOSE(S):

To record registration, vaccination, and/or treatment of animals; to compile statistical data; and to identify animals registered with the Veterinary Treatment Facility. Used by veterinarians and health care authorities to identify the animal, verify ownership, record history, and to insure veterinary care, treatment and immunizations provided to animals of authorized owners is recorded; to compile statistical data; conduct research; teach; assist in law enforcement, to include investigation and litigation; and evaluate the care provided.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The information may be used to aid in preventive health and communicable disease control programs, report medical conditions required by law to Federal, state, and local agencies.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

By name and Social Security Number of the animal's owner.

SAFEGUARDS:

Records are maintained in buildings which are locked when unattended and are accessed only by authorized personnel having an official need-to-know.

RETENTION AND DISPOSAL:

Destroy upon death of the animal, transfer of owner, or 2 years after last entry in the record.

SYSTEM MANAGER(S) AND ADDRESS:

Chief Information Officer, Office of the Surgeon General, U.S. Army Medical Command, ATTN: MCIM, 2050 Worth Road, Suite 13, Fort Sam Houston, TX 78234–6013.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized.

Animal owner should provide the full name, Social Security Number, home address and telephone number and the animal's rabies vaccination number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized.

Animal owner should provide the full name, Social Security Number, home address and telephone number and the animal's rabies vaccination number.

Personal visits may be made to the veterinary facility where animal was treated. Owner must provide personal identification such as a valid military identification card or driver's license.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the animal owner, veterinarian reports, and similar or related documents.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 01–410 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DOD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Army is altering a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended. The alteration adds a new category of individuals covered, *i.e.*, reserve personnel.

DATES: This proposed action will be effective without further notice on February 7, 2001 unless comments are received which result in a contrary determination.

ADDRESSES: Records Management Division, U.S. Army Records Management and Declassification Agency, ATTN: TAPC–PDD–RP, Stop 5603, Ft. Belvoir, VA 22060–5603.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Thornton at (703) 806–4390 or DSN 656–4390 or Ms. Christie King at (703) 806–3711 or DSN 656–3711.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on December 19, 2000, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: December 20, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0635–5 TAPC

SYSTEM NAME:

Separation Transaction Control/ Records Transfer System (February 22, 1993, 58 FR 10002).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Active duty enlisted and reserve personnel separated from military service (excluding active duty for military for training) and all personnel immediately reenlisting after separation.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Name, Social Security Number, rank, eligibility for reenlistment, character of separation, program designator, date and location of separation, reenlistment, moral waiver and specialty, and DD Form 214, Certificate of Discharge of Release from Active Duty.'

PURPOSE(S):

Delete entry and replace with 'To monitor separations of active duty and reserve personnel as a means of controlling strength and record accountability, and re-enlistment processing, and to ensure separation documents are filed in official military record.

* * * * *

STORAGE:

Delete entry and replace with 'Magnetic tapes/discs and electronic storage media.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Separation records and related documents are maintained for six months and then destroyed.

Reenlistment eligibility records are forwarded for incorporation into the military personnel jacket, destroy upon reenlistment of individual.

Military Personnel Transition Point Processing Master File (Disposition pending. Until the National Archives and Records Administration has approved the retention and disposal schedule for these records, treat as permanent.'

* * * * *

A0635–5 TAPC

SYSTEM NAME:

Separation Transaction Control/ Records Transfer System.

SYSTEM LOCATION:

Commander, U.S. Total Army Personnel Command, Retirements and Separations Branch, 200 Stovall Street, Alexandria, VA 22332–0478;

U.S. Army Enlisted Records and Evaluation Center, Fort Benjamin Harrison, IN 46249–5301;

U.S. Army Reserve Components and Personnel Center, 9700 Page Avenue, St. Louis, MO 63132–5200.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty enlisted and reserve personnel separated from military service (excluding active duty for military for training) and all personnel immediately re-enlisting after separation.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, rank, eligibility for re-enlistment, character of separation, program designator, date and location of separation, reenlistment, moral waiver and specialty, and DD Form 214, Certificate of Discharge of Release from Active Duty.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army; Army Regulation 601–280, Army Retention Program; Army Regulation 635–200, Enlisted Personnel; and E.O. 9397 (SSN).

PURPOSE(S):

To monitor separations of active duty and reserve personnel as a means of controlling strength and record accountability, and re-enlistment processing, and to ensure separation documents are filed in official military record.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Magnetic tapes/discs and electronic storage media.

RETRIEVABILITY:

By name and/or Social Security Number.

SAFEGUARDS:

Records are protected by physical security devices, guards, computer software and hardware safeguard features, and personnel clearances.

RETENTION AND DISPOSAL:

Separation records and related documents are maintained for six months and then destroyed.

Reenlistment eligibility records are forwarded for incorporation into the

military personnel jacket, destroy upon reenlistment of individual.

Military Personnel Transition Point Processing Master File records are retained in current file area, treat as permanent until National Archives and Records Administration disposition is approved.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, U.S. Total Army Personnel Command, Retirements and Separations Branch, 200 Stovall Street, Alexandria, VA 22332–0478.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Commander, U.S. Total Army Personnel Command, Retirements and Separations Branch, 200 Stovall Street, Alexandria, VA 22332–0478.

Individual should provide the full name, Social Security Number, military status, and if separated, date of separation.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Commander, U.S. Total Army Personnel Command, Retirements and Separations Branch, 200 Stovall Street, Alexandria, VA 22332–0478.

Individual should provide the full name, Social Security Number, military status, and if separated, date of separation.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From relevant Army records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 01–411 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to amend systems of records.

SUMMARY: The Department of the Army is amending two systems of records notices in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on February 7, 2001 unless comments are received which result in a contrary determination.

ADDRESSES: Records Management Division, U.S. Army Records Management and Declassification Agency, ATTN: TAPC–PDD–RP, Stop 5603, Ft. Belvoir, VA 22060–5603.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Thornton at (703) 806–4390 or DSN 656–4390 or Ms. Christie King at (703) 806–3711 or DSN 656–3711.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the records systems being amended are set forth below followed by the notices, as amended, published in their entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: December 20, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0025–6USASC

SYSTEM NAME:

Military Affiliate Radio System (August 7, 1997, 62 FR 42523).

CHANGES:

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CATEGORIES OF RECORDS IN THE SYSTEM:

Replace last sentence with the following 'Federal Communications Commission, Army Military Affiliate Radio System call-sign, relevant inquiries, records and reports.'

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete second paragraph and replace with 'Information may be disclosed to federal supply agencies in connection with individual's participation in the Army MARS Equipment Program.'

* * * * *

STORAGE:

Delete entry and replace with 'Cards, paper records in file folders, discs, listings and electronic storage media'.

RETRIEVABILITY:

Delete entry and replace with 'By member's name, amateur and or Military Affiliate Radio call signs.'

SAFEGUARDS:

Delete entry and replace with 'Information is maintained in buildings accessible to authorized personnel in the performance of their duties. Automated records are further protected by a password assigned to designated personnel.'

* * * * *

A0025–6USASC

SYSTEM NAME:

Military Affiliate Radio System (August 7, 1997, 62 FR 42523).

SYSTEM LOCATION:

U.S. Army Signal Command, Fort Huachuca, AZ 85613–5000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals having a valid amateur radio station license issued by the Federal Communications Commission, Army Military Affiliate Radio System call-sign, relevant inquiries, records and reports.

CATEGORIES OF RECORDS IN THE SYSTEM:

Applicant's name, home address and telephone number, licensing data and call-sign provided by Federal Communications Commission, Army MARS call-sign, relevant inquiries/records and reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army: DoD Directive 4650.2, Military Affiliate Radio System; Army Regulation 25–6, Military Affiliate Radio System; and E.O. 9397 (SSN).

PURPOSE(S):

To provide a potential reserve of trained radio communications personnel for military duty when needed and/or to provide auxiliary communications for military, civil, and/or disaster officials during periods of emergency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the

DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Information may be disclosed to federal supply agencies in connection with individual's participation in the Army MARS Equipment Program.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Cards, paper records in file folders, discs, listings and electronic storage media.

RETRIEVABILITY:

By member's name, amateur and or Military Affiliate Radio call signs.

SAFEGUARDS:

Information is maintained in buildings accessible to authorized personnel in the performance of their duties. Automated records are further protected by a password assigned to designated personnel.

RETENTION AND DISPOSAL:

Destroy on each renewal or two years after termination of membership.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, U.S. Army Signal Command, Fort Huachuca, AZ 95613–5000.

NOTIFICATION PROCEDURE:

Individual seeking to determine whether information about themselves is contained in this system should address written inquiries to the Commander, U.S. Army Signal Command, Fort Huachuca, AZ 95613–5000.

Individual should provide the name under which licensed is the Army Military Affiliate Radio System program, amateur and or Military Affiliate Radio System call sign, present address, call sign, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this record system should address written inquiries to the Commander, U.S. Army Signal Command, Fort Huachuca, AZ 95613–5000.

Individual should provide the name under which licensed is the Army Military Affiliate Radio System program, amateur and or Military Affiliate Radio System call sign, present address, call sign, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual and the Federal Communications Commission.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0672–5–1 TAPC

SYSTEM NAME:

Military Awards Case File (February 22, 1993, 58 FR 10002).

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'A0600–8–22 TAPC'.

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. Chapters 57 and 357, Decorations and Awards; 10 U.S.C. 3013, Secretary of the Army; Army Regulation 600–8–22, Military Awards; and E.O. 9397 (SSN).'

* * * * *

STORAGE:

Delete entry and replace with 'Paper records in file folders and electronic storage media.'

RETRIEVABILITY:

Delete entry and replace with 'By nominee's name, service number and/or Social Security Number.'

SAFEGUARDS:

Delete entry and replace with 'Records are maintained in locked file cabinets in secure buildings and are accessible only to designated personnel in the performance of their assigned duties.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Documents related to providing information about awards given to individuals, *i.e.* announcements, lists, cards, and similar information destroy after 2 years. Approval and disapproval authority: Approved awards relating to wartime and combat activities are held permanently; Approved peacetime awards and all disapproved awards are retired to the Washington National Records Center and are destroyed after 25 years. Offices not within the disapproval or approval authority maintain records for 2 years then destroy. Proficiency awards are destroyed on transfer of the individual. Public award cases: Exercising approval authority maintain records for 56 years then destroy; Non-approval authority offices maintain records for 2 years then destroy. Special achievement awards: Exercising awarding authority maintain records for 5 years then destroy; Non-Award authority offices maintain for 2 years then destroy.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Commander, U.S. Total Army Personnel Command, Awards Policy Division, 200 Stovall Street, Alexandria, VA 22332–0471.'

* * * * *

A0600–8–22 TAPC

SYSTEM NAME:

Military Awards Case File.

SYSTEM LOCATION:

U.S. Total Army Personnel Command, 200 Stovall Street, Alexandria, VA 22332–0471. Segments exist at Army commands which have been delegated authority for approval of an award. Official mailing addresses may be obtained from the U.S. Total Army Personnel Command, 200 Stovall Street, Alexandria, VA 22332–0471.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military personnel on active duty, members of reserve components, U.S. civilians serving with U.S. Army units in a combat zone, and deceased former members of the U.S. Army.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files include recommendations for an award; endorsements; award board approvals/disapprovals; citation texts; Department of Army letter orders/general orders; related papers supporting the award; correspondence among the Army; service member, and individuals having knowledge/information relating to the service member concerned or the act or achievement for which an award is recommended.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. Chapters 57 and 357, Decorations and Awards; 10 U.S.C. 3013, Secretary of the Army; Army Regulation 600–8–22, Military Awards; and E.O. 9397 (SSN).

PURPOSE(S):

To consider individual nominations for awards and/or decorations; record final action; maintain individual award case files.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Information may be disclosed to public and private organizations including news media, which grant or publicize awards or honors.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic storage media.

RETRIEVABILITY:

By nominee's name, service number and/or Social Security Number.

SAFEGUARDS:

Records are maintained in locked file cabinets in secure buildings and are accessible only to designated personnel in the performance of their assigned duties.

RETENTION AND DISPOSAL:

Documents related to providing information about awards given to individuals, *i.e.,* announcements, lists, cards, and similar information destroy after 2 years. Approval and disapproval authority: Approved awards relating to wartime and combat activities are held permanently; Approved peacetime awards and all disapproved awards are retired to the Washington National Records Center and are destroyed after 25 years. Offices not within the disapproval or approval authority maintain records for 2 years then destroy. Proficiency awards are destroyed on transfer of the individual. Public award cases: Exercising approval authority maintain records for 56 years then destroy; Non-approval authority offices maintain records for 2 years then destroy. Special achievement awards: Exercising awarding authority maintain records for 5 years then destroy; Non-Award authority offices maintain for 2 years then destroy.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, U.S. Total Army Personnel Command, Awards Policy Division, 200 Stovall Street, Alexandria, VA 22332–0471.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Commander, U.S. Total Army Personnel Command, Awards Policy Division, 200 Stovall Street, Alexandria, VA 22332–0471.

Individual should provide the full name, service number and/or Social Security Number, grade and branch of service, name of award/honor, and current address.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Commander, U.S. Total Army Personnel Command, Awards Policy Division, 200 Stovall Street, Alexandria, VA 22332–0471.

Individual should provide the full name, service number and/or Social Security Number, grade and branch of service, name of award/honor, and current address.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From Recommendation for Awards (DA Form 638) with supporting records, forms, statements, letters, and similar documents originated by persons other than the awardee and other individuals having information useful in making an award determination.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 01–413 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to alter systems of records.

SUMMARY: The Department of the Army proposes to alter two systems of records notices in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on February 7, 2001, unless comments are received that would result in a contrary determination.

ADDRESSES: Records Management Division, U.S. Army Records Management and Declassification Agency, ATTN: TAPC-PDD-RP, Stop 5603, Ft. Belvoir, VA 22060–5603.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Thornton at (703) 806–4390 or DSN 656–4390 or Ms. Christie King at (703) 806–3711 or DSN 656–3711.

SUPPLEMENTARY INFORMATION: The Department of the Army notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act was submitted on December 19, 2000, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (61 FR 6427, February 20, 1996).

Dated: December 21, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0614–100/200 USMA

SYSTEM NAME:

Evaluation/Assignment of Academic Instructors (February 22, 1993, 58 FR 10002).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Civilian and military personnel who apply and/or serve on the Staff and Faculty, U.S. Military Academy.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Individual's application consisting of name, grade or position, Social Security Number, educational and professional qualifications such as the Graduate Record Examination (GRE) or Graduate Management Admission Test (GMAT); evaluations; Officer Record Briefs (military only); personnel actions; appointments; official photographs; curriculum vitae; letters of endorsement; award recommendations; assignment orders; application/acceptance for advanced civil schooling; correspondence between the U.S.

Military Academy and the Total Army Personnel Command; and other relevant documents.'

PURPOSE(S):

Delete entry and replace with 'Used by the U.S. Military Academy Dean of Academic Board and department heads to assess qualifications and suitability, and manage civilian and military personnel for assignment to the Staff and Faculty, U.S. Military Academy.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Information is available only to designated people who have a need-to-know.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Disposition pending (until the National Archive and Records Administration approves the retention and disposition schedule, treat records as permanent).'

* * * * *

A0614–100/200 USMA

SYSTEM NAME:

Evaluation/Assignment of Academic Instructors.

SYSTEM LOCATION:

Associate Dean for Plans and Resources, Office of the Dean, U.S. Military Academy, Dean of Academic Board, West Point, NY 10996–5000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilian and military personnel who apply and/or serve on the Staff and Faculty, U.S. Military Academy.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's application consisting of name, grade or position, Social Security Number, educational and professional qualifications such as the Graduate Record Examination (GRE) or Graduate Management Admission Test (GMAT); evaluations; Officer Record Briefs (military only); personnel actions; appointments; official photographs; curriculum vitae; letters of endorsement; award recommendations; assignment orders; application/acceptance for advanced civil schooling; correspondence between the U.S. Military Academy and the Total Army Personnel Command; and other relevant documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 4334, Command and Supervision; 10 U.S.C. 4337, Civilian Faculty and E.O. 9397 (SSN).

PURPOSE(S):

Used by the U.S. Military Academy Dean of Academic Board and department heads to assess qualifications and suitability, and manage civilian and military personnel for assignment to the Staff and Faculty, U.S. Military Academy.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic storage medium.

RETRIEVABILITY:

By individual's name and Social Security Number.

SAFEGUARDS:

Information is available only to designated people who have a need-to-know.

RETENTION AND DISPOSAL:

Disposition pending (until the National Archive and Records Administration approves the retention and disposition schedule, treat records as permanent).

SYSTEM MANAGER(S) AND ADDRESS:

Associate Dean for Plans and Resources, Office of the Dean, Dean of Academic Board, West Point, NY 10996–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Associate Dean for Plans and Resources, Office of the Dean, U.S. Military Academy, Dean of Academic Board, West Point, NY 10996–5000.

Individual should provide the full name, Social Security Number, sufficient details to locate records, current mailing address, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Associate Dean for Plans and Resources, Office of the Dean, U.S. Military Academy, Dean of Academic Board, West Point, NY 10996–5000.

Individual should provide the full name, Social Security Number, sufficient details to locate records, current mailing address, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual; official Army or other Service records; academic institutions; letters of endorsement from third parties; U.S. Army Military Personnel Center; similar relevant documents.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0635–40 TAPC

SYSTEM NAME:

Temporary Disability Retirement Master List (TDRL) (February 22, 1993, 58 FR 10002).

CHANGES:

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 1376, Temporary Disability Retired Lists; 10 U.S.C. 3013, Secretary of the Army; Army Regulation 635–40, Physical Evaluation for Retention, Retirement of Separation; and E.O. 9397 (SSN).

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph 'To the Department of Veterans Affairs to facilitate claims for veteran disability benefits.'

STORAGE:

Paper records in file folders, automated database, computer printouts, magnetic tapes and disks.

RETRIEVABILITY:

Add 'name' to entry.

SAFEGUARDS:

Add to entry 'Records are retained in secure offices within secure buildings.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'From the individual, medical treatment facilities, and other Army records and reports.'

* * * * *

A0635–40 TAPC

SYSTEM NAME:

Temporary Disability Retirement Master List (TDRL).

SYSTEM LOCATION:

PRIMARY LOCATION:

Chief, U.S. Army Physical Disability Agency, Walter Reed Army Medical Center, 6900 Georgia Avenue, NW, Building 7, Washington, DC 20307–5001.

SECONDARY LOCATION:

Defense Finance and Accounting Service, 8899 East 56th Street, Indianapolis, IN 46249–5000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Army personnel who are on temporary disability retirement.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains, Social Security Number, name, address, Department of Army special order number, percentage of disability, doctor code, re-examination date, date placed on TDRL, hospital code, travel code, Army component, pay termination code, requirement for board code, record control number, hospital name and address.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 1376, Temporary Disability Retired Lists; 10 U.S.C. 3013, Secretary of the Army; Army Regulation 635–40, Physical Evaluation for Retention, Retirement of Separation; and E.O. 9397 (SSN).

PURPOSE(S):

To coordinate with medical treatment facilities for scheduling medical examinations; to issue travel orders for individual to report to medical treatment facility for annual medical examination; to determine individual's status by the end of the fifth year of being on the TDRL, *i.e.,* whether individual is to be permanently retired for disability, or returned to duty.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Department of Veterans Affairs to facilitate claims for veteran disability benefits.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in medical treatment facilities; magnetic tape, disc.

RETRIEVABILITY:

By name, Social Security Number and date.

SAFEGUARDS:

Access to all records is restricted to individuals having need therefor in the performance of duties. Automated media are further protected by authorized password for system, controlled access to operation rooms and controlled output distribution. Records are retained in secure offices within secure buildings.

RETENTION AND DISPOSAL:

Information is maintained for 3 years after the member is found physically fit, separates or retires.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, U.S. Army Physical Disability Agency, Walter Reed Army Medical Center, 6900 Georgia Avenue, NW, Building 7, Washington, DC 20307–5001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Chief, U.S. Army Physical Disability Agency, Walter Reed Army Medical Center, 6900 Georgia Avenue, NW, Building 7, Washington, DC 20307–5001.

Individual should provide the full name, Social Security Number, current address and telephone number, and signature.

Inquiries are restricted to issues relating to the Temporary Disability Retirement List only; issues of pay must be made at the Defense Finance and Accounting Service, 8899 East 56th Street, Indianapolis, IN 46249–5000.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Chief, U.S. Army Physical Disability Agency, Walter Reed Army Medical Center, 6900 Georgia Avenue, NW, Building 7, Washington, DC 20307–5001.

Individual should provide the full name, Social Security Number, current address and telephone number, and signature.

Inquiries are restricted to issues relating to the Temporary Disability Retirement List only; issues of pay must be made at the Defense Finance and Accounting Service, 8899 East 56th Street, Indianapolis, IN 46249–5000.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, medical treatment facilities, and other Army records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 01–414 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–U

DEPARTMENT OF DEFENSE

Defense Logistics Agency

Privacy Act of 1974; Computer Matching Program

AGENCY: Defense Manpower Data Center, Defense Logistics Agency, DOD.

ACTION: Notice of a computer matching program.

SUMMARY: Subsection (e)(12) of the Privacy Act of 1974, as amended, (5 U.S.C. 552a) requires agencies to publish advance notice of any proposed or revised computer matching program by the matching agency for public comment. The Department of Defense (DoD), as the matching agency under the Privacy Act, is hereby giving notice to the record subjects of a computer matching program between Office of Personnel Management (OPM) and DoD that records are being matched by computer. The goal of the match is to identify individuals who are improperly receiving credit for military service in their civil service annuities or annuities based on the ''guaranteed minimum'' disability formula. This match will identify and/or prevent erroneous payments under the CSRA and FERSA Pay system.

DATES: This proposed action will become effective February 7, 2001 and

the computer matching will proceed accordingly without further notice, unless comments are received which would result in a contrary determination or if the Office of Management and Budget or Congress objects thereto. Any public comment must be received before the effective date.

ADDRESSES: Any interested party may submit written comments to the Director, Defense Privacy Office, 1941 Jefferson Davis Highway, Suite 920, Arlington, VA 22202–4502.

FOR FURTHER INFORMATION CONTACT: Mr. Vahan Moushegian, Jr. at (703) 607–2943.

SUPPLEMENTARY INFORMATION: Pursuant to subsection (o) of the Privacy Act of 1974, as amended, (5 U.S.C. 552a), the DoD and OPM have concluded an agreement to conduct a computer matching program between the agencies. The purpose of the match is to exchange personal data between the agencies for identification of individuals who are improperly receiving military retired pay.

A copy of the computer matching agreement between the OPM and DoD is available upon request to the public. Requests should be submitted to the address caption above or to the Chief, Retirement Inspection Branch, Room 2309, Retirement and Insurance Service, Office of Personnel Management, 1900 E Street, NW, Washington, DC 20415.

Set forth below is a public notice of the establishment of the computer matching program required by paragraph 6.c. of the Office of Management and Budget Guidelines on computer matching published on June 19, 1989, at 54 FR 25818.

The matching agreement, as required by 5 U.S.C. 552a(r) of the Privacy Act, and an advance copy of this notice were submitted on December 20, 2000, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget pursuant to paragraph 4d of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records about Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: December 22, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Notice of a Computer Matching Program between the Office of Personnel Management, and the Department of Defense for Retired Military Pay.

A. *Participating agencies:* Participants in this computer matching program are the Office of Personnel Management (OPM) and the Defense Manpower Data Center (DMDC), Department of Defense (DoD). The Office of Personnel Management is the source agency, *i.e.,* the activity disclosing the records for the purpose of the match. The DMDC is the specific recipient activity or matching agency, *i.e.,* the agency that actually performs the computer matching.

B. *Purpose of the match:* The purpose of this agreement is to establish the conditions for a computer matching program between the OPM as the source agency and DMDC as the recipient agency. The goal of the match is to identify individuals who are improperly receiving credit for military service in their civil service annuities or annuities based on the ''guaranteed minimum'' disability formula. This match will identify and/or prevent erroneous payments under the CSRA and FERSA Pay system.

C. *Authority for conducting the match:* It is OPM's responsibility to monitor retirement and survivor benefits paid under 5 U.S.C. 8331 (CSRA), *et seq.* and 5 U.S.C. 8401 (FESRA), *et seq.* Specifically, 5 U.S.C. 8332 is the legal authority for CSRA and 5 U.S.C. 8411 is the legal authority for FESRA for determining whether military service may be credited for civil service retirement purposes.

D. *Records to be matched:* The systems of records described below contain an appropriate routine use provisions which permits disclosure of information between agencies.

OPM will use the system of records identified as OPM/Central-1, 'Civil Service Retirement and Insurance Records,' published at 60 FR 63081, December 8, 1995, as amended at 63 FR 45881, August 27, 1998 and at 65 FR 25775, May 3, 2000.

DoD will use the system of records identified as S322.10 DMDC, 'Defense Manpower Data Center Data Base,' published at 65 FR 43302, July 13, 2000.

E. Description of computer matching program: The OPM will provided DMDC with an electronic file which contains specified data elements of individual CSRA and FESRA annuitants. Upon receipt of the electronic file, DMDC will perform a computer match using all nine digits of the SSN's in the OPM file against the DMDC computer database on military retired pay data.

The data will be matched to identify those individuals who are being paid in apparent violation of law, *i.e.,* the civil service annuity is based on military service other than that which was awarded (1) on account of a service connected disability incurred in combat with an enemy of the United States; (2) on account of a service connected disability caused by an instrumentality of war and incurred in the line of duty during a period of war; or (3) based on non-regular (*i.e.,* reserve) service under the provisions of 10 U.S.C. 12731–12739.

The data elements provided by OPM for the match file will contain the names, addresses, social security number, date of birth, OPM retirement claim number, OPM provision retired codes, and annuity payment and service data of individuals currently receiving benefits from OPM.

The DMDC database contains approximately 1.9 million records of military retired personnel.

F. Individual notice and opportunity to contest: Due process procedures will be provided by OPM to those individuals matched (hits) consisting of OPM'S verification of debt; a minimum of 30-day written notice to the debtor explaining the debtor's rights; opportunity for the debtor to examine and copy OPM documentation relating to the debt; provision for debtor to seek the OPM review of the debt (or in the case of the salary offset provision, opportunity for a hearing before an individual who is not under the supervision or control of the agency); and opportunity for the individual to enter into a written agreement satisfactory to the OPM for repayment. Only when all of the steps have been taken will OPM disclose information, pursuant to a routine use, to effect an administrative or salary offset. Unless the individual notifies OPM within 30 days from the date of the notice, OPM will infer that the data provided the individual is accurate and correct and will take the next step, as authorized by law, to recoup the delinquent debt.

G. Inclusive dates of the matching program: This computer matching program is subject to review by the Office of Management and Budget and Congress. If the mandatory 30 day period for public comment has expired and if no objections are raised by either Congress or the Office of Management and Budget within 40 days of being notified of the proposed match, the computer matching program becomes effective and the respective agencies may begin the exchange of data at a mutually agreeable time and will be repeated on an bi-annual basis. By agreement between OPM and DoD, the matching program will be in effect and

continue for 18 months with an option to extend for 12 additional months unless one of the parties to the agreement advises the other by written request to terminate or modify the agreement.

H. Address for receipt of public comments or inquiries: Director, Defense Privacy Office, 1941 Jefferson Davis Highway, Suite 920 Arlington, VA 22202–4502. Telephone (703) 607–2943.

[FR Doc. 01–418 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Navy

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Navy proposes to alter seven system of records notices in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on February 7, 2001 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (N09B30), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545 or DSN 325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act was submitted on December 19, 2000, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (61 FR 6427, February 20, 1996).

Dated: December 20, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N05810–2

SYSTEM NAME:

Military Justice Correspondence and Information File (May 7, 1999, 64 FR 24619).

CHANGES:

* * * * *

CATEGORY OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Files contain background information relevant to specific military justice cases, copies of incoming and outgoing correspondence relating to military justice cases, and may contain information relating to the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victim's Rights and Restitution Act of 1990.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''5 U.S.C. 301, Departmental Regulations and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.''

PURPOSE(S):

Add a new paragraph ''To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph ''To victims and witnesses to comply with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

* * * * *

N05810–2

SYSTEM NAME:

Military Justice Correspondence and Information File.

SYSTEM LOCATION:

Office of the Judge Advocate General (Code 20), Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047 and duplicate copies may be maintained in local legal office file.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty, retired, and discharged Navy and Marine Corps personnel who were the subject of military justice proceedings or investigations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files contain background information relevant to specific military justice cases, copies of incoming and outgoing correspondence relating to military justice cases, and may contain information relating to the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victim's Rights and Restitution Act of 1990.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.

PURPOSE(S):

To provide a record of individual inquiries and JAG responses concerning military justice related matters, and to maintain background information on military justice matters to assist in responding to inquiries.

To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To victims and witnesses to comply with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

The DoD ''Blanket Routine Uses'' that appear at the beginning of the Navy's compilation of system notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, binder-notebooks, and computer hard drive and floppy disks.

RETRIEVABILITY:

Files are kept in alphabetical order according to the last name of the individual who is the subject of the file.

SAFEGUARDS:

Files are maintained in file cabinets and other storage devices under the control of authorized personnel during working hours; the office space in which the file cabinets and storage devices are located is locked outside of working hours.

RETENTION AND DISPOSAL:

Records are maintained in office for two years and then forwarded to the Federal Records Center, Suitland, MD 20409 for storage; files containing background material are maintained on computer hard drive for two years and then purged.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Judge Advocate General (Military Justice), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Deputy Assistant Judge Advocate General (Criminal Law), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

Information may be obtained by written request stating the full name of the individual concerned. Written requests must be signed by the requesting individual. Personal visits may be made to the Criminal Law Division, Office of the Judge Advocate General at the above address. Individuals making such visits should be able to provide some acceptable identification, *e.g.,* Armed Forces' identification card, driver's license, etc.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves should address written inquiries to the Deputy Assistant Judge Advocate General (Criminal Law), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

Information may be obtained by written request stating the full name of the individual concerned. Written requests must be signed by the requesting individual. Personal visits may be made to the Criminal Law Division, Office of the Judge Advocate General at the above address. Individuals making such visits should be able to provide some acceptable identification, *e.g.,* Armed Forces' identification card, driver's license, etc.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Records in this system are compiled from information received from naval field offices, records of trial, and correspondence.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05813–3

SYSTEM NAME:

Records of Trial of General Courts-Martial (August 3, 1999, 64 FR 42106).

CHANGES:

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 865; and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.''

PURPOSE(S):

Add a new paragraph ''To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph ''To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.''

* * * * *

N05813–3

SYSTEM NAME:

Records of Trial of General Courts-Martial.

SYSTEM LOCATION:

Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty Navy and Marine Corps personnel tried by general courts-martial.

CATEGORIES OF RECORDS IN THE SYSTEM:

General courts-martial records of trial.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 865; and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.

PURPOSE(S):

To complete appellate review as required under 10 U.S.C. 866, 867, 869 and provide central repository accessible to the public who may request information concerning the appellate review or want copies of individual public records.

To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Files are kept by Navy courts-martial number and each case is cross-

referenced by an index card which is filed in alphabetical order according to the last name of the individual concerned.

SAFEGUARDS:

Files are maintained in file cabinets under the control of authorized personnel during working hours; the office space in which the file cabinets are located is locked outside official working hours.

RETENTION AND DISPOSAL:

Records are maintained in office for three years and then forwarded to the Washington Federal Records Center, 4205 Suitland Road, Suitland, MD 20409 for storage.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Judge Advocate General (Military Law), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system contains information about themselves should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Proceedings by a general courts-martial.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05813–5

SYSTEM NAME:

Record of Trial of Special Courts-Martial Resulting in Bad Conduct Discharges or Concerning Officers (June 8, 1999, 64 FR 30497)

CHANGES:

* * * * *

PURPOSE(S):

Add a new paragraph ''To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

Add a new paragraph ''To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.''

* * * * *

N05813–5

SYSTEM NAME:

Record of Trial of Special Courts-Martial Resulting in Bad Conduct Discharges or Concerning Officers.

SYSTEM LOCATION:

Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps personnel tried by special courts-martial and awarded a bad conduct discharge, and all Navy and Marine Corps commissioned officers tried by special courts-martial.

CATEGORIES OF RECORDS IN THE SYSTEM:

Special courts-martial which resulted in a bad conduct discharge, or involving commissioned officers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 865; 10 U.S.C. 866(b); and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.

PURPOSE(S):

To complete appellate review as required under 10 U.S.C. 866(b) and provide central repository accessible to the public who may request information concerning the appellate review or want copies of individual public records.

To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Files are kept by Navy courts-martial number and each case is cross-

referenced by an index card which is filed in alphabetical order according to the last name of the individual concerned.

SAFEGUARDS:

Files are maintained in file cabinets and other storage devices under the control of authorized personnel during working hours; the office space in which the file cabinets and storage devices are located is locked outside official working hours.

RETENTION AND DISPOSAL:

Records are maintained in office for three years and then forwarded to the Washington Federal Records Center, 4205 Suitland Road, Suitland, MD 20409 for storage.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Judge Advocate General (Military Justice), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system contains information about themselves should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Special courts-martial proceedings.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05813–6

SYSTEM NAME:

Summary and Non-BCD Special Courts-Martial Records of Trial (June 8, 1999, 64 FR 30497).

CHANGES:

* * * * *

PURPOSE(S):

Add a new paragraph ''To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph ''To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.''

* * * * *

N05813–6

SYSTEM NAME:

Summary and Non-BCD Special Courts-Martial Records of Trial.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps enlisted personnel tried by summary courts-martial or by special courts-martial which did not result in a bad conduct discharge (BCD).

CATEGORIES OF RECORDS IN THE SYSTEM:

Summary courts-martial and non-BCD special courts-martial records of trial.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 865; and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.

PURPOSE(S):

To complete appellate review as required under 10 U.S.C. 864(a) and provide repositories accessible to the public who may request information concerning the appellate review or want copies of individual public records.

To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Type of courts-martial, date, command which convened the courts-martial, name of individual defendant, and command which completed the supervisory authority's action.

SAFEGUARDS:

Files are maintained in file cabinets and other storage devices under the control of authorized personnel during working hours; the office space in which the file cabinets and storage devices are located is locked outside official working hours.

RETENTION AND DISPOSAL:

Records are retained for two years after final action by officers having supervisory authority over shore activities, and for three months by officers having supervisory authority over fleet activities. At the termination of the appropriate retention period, records are forwarded for storage to the National Personnel Records Center (Military Personnel Records), GSA, 9700 Page Avenue, St. Louis, MO 63132–5100. Records are destroyed 15 years after final action has been taken.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Judge Advocate General (Military Justice), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047 or appropriate officer having supervisory authority over the naval activity which convened the court-martial.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Division Director, Administrative Support Division, Navy-Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should include the full name of the individual concerned, the type of courts-martial (summary or special), the name of the command which held the courts-martial, and the date of the courts-martial proceedings. Written requests must be signed by the requesting individual.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Division Director, Administrative Support Division, Navy-Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should include the full name of the individual concerned, the type of courts-martial (summary or special), the name of the command which held the courts-martial, and the date of the courts-martial proceedings. Written requests must be signed by the requesting individual.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Proceedings of summary courts-martial and special courts-martial which did not result in a bad conduct discharge.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05814–3

SYSTEM NAME:

Courts-Martial Information (August 3, 1999, 64 FR 42106).

CHANGES:

* * * * *

PURPOSE(S):

Add a new paragraph ''To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph ''To victims and witnesses to comply with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

* * * * *

N05814–3

SYSTEM NAME:

Courts-Martial Information.

SYSTEM LOCATION:

Administrative Support Division (Code 40), Navy-Marine Corps Appellate Review Activity, Office of the Judge Advocate General, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps personnel tried by general courts-martial and by special courts-martial when the special courts-martial sentence, as finally approved, includes a punitive discharge.

CATEGORIES OF RECORDS IN THE SYSTEM:

Courts-martial information on special courts-martial if sentence, as finally approved, includes a punitive discharge and all general courts-martial including name, Social Security Number, pleas, convening authority action, supervisory authority action, and Court of Military Review action. Information is available from 1970 through 1986 only.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures; and E.O. 9397 (SSN).

PURPOSE(S):

To collect data on general and bad conduct discharge special courts-martial.

To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To governmental, public and private organizations and individuals, as required.

To victims and witnesses to comply with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records also apply to this system.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Index card file.

RETRIEVABILITY:

Index cards are filed by year appellate review of the case was completed and alphabetically by last name within a given year.

SAFEGUARDS:

Office is located in a secure building which is guarded 24 hours a day. Admission is allowed only to personnel on official business and authorized visitors.

RETENTION AND DISPOSAL:

Indefinite.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Judge Advocate General (Military Justice), Office of the Judge Advocate General, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system contains information about themselves should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Navy Judge Advocate General Form 5813/1.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05814–4

SYSTEM NAME:

Article 69(b) Petitions (May 28, 1999, 64 FR 29009).

CHANGES:

* * * * *

PURPOSE(S):

Add a new paragraph ''To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph ''To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.''

* * * * *

N05814–4

SYSTEM NAME:

Article 69(b) Petitions.

SYSTEM LOCATION:

Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps personnel who were tried by courts-martial which were not reviewed by the Navy-Marine Corps Court of Criminal Appeals and when such service member has petitioned the Judge Advocate General pursuant to Article 69(b), Uniform Code of Military Justice, for review.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files contain individual service member's petition together with all forwarding endorsements and copy of action taken by the Judge Advocate General with supporting memorandum.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; Article 69, Uniform Code of Military Justice, 10 U.S.C. 869) and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.

PURPOSE(S):

To complete appellate review as required under 10 U.S.C. 869(b) and to provide a central repository accessible to the public who may request information concerning the appellate review or want copies of individual public records.

To provide information and support to victims and witnesses in compliance with the Victim and Witness Assistance Program, the Sexual Assault Prevention and Response Program, and the Victims' Rights and Restitution Act of 1990.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Records are maintained in chronological calendar order with alphabetical cross-referencing system.

SAFEGUARDS:

Files are maintained in file cabinets and other storage devices under the control of authorized personnel during working hours; the office spaces in which the file cabinets and storage

devices are located are locked outside official working hours.

RETENTION AND DISPOSAL:

Records are maintained in office for four years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Judge Advocate General (Military Justice), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system contains information about themselves should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, e.g., Armed Forces identification card, driver's license, etc.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

The records comprise of the following source materials: (1) Petitions for relief, (2) forwarding endorsements thereon by petitioner's commanding officer and convening/supervisory authorities of courts-martial (above information is omitted if petitioner is former service member), and (3) action of the Judge Advocate General on petition.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

N05814–5

SYSTEM NAME:

Article 73 Petitions for New Trial (June 8, 1999, 64 FR 30497).

CHANGES:

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph ''To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.''

N05814–5

SYSTEM NAME:

Article 73 Petitions for New Trial.

SYSTEM LOCATION:

Administrative Support Division, Navy and Marine Corps Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Navy and Marine Corps personnel who submitted petitions for new trial to the Judge Advocate General within two years after approval of their courts-martial sentence by the convening authority but after their case had been reviewed by the Navy-Marine Corps Court of Criminal Appeals or the Court of Appeals for the Armed Forces, if appropriate.

CATEGORIES OF RECORDS IN THE SYSTEM:

The petition for new trial, the forwarding endorsements if the petition was submitted via the chain of command, and the action of the Judge Advocate General on the petition.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; Article 73, Uniform Code of Military Justice, 10 U.S.C. 873); and 42 U.S.C. 10601 *et seq.*, Victim's Rights and Restitution Act of 1990 as implemented by DoD Instruction 1030.2, Victim and Witness Assistance Procedures.

PURPOSE(S):

To provide a record of individual petitions in order to answer inquiries from the individual concerned and to provide additional advice to commands involved when and if such petitions are granted.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Files are kept in alphabetical order according to the last name of the individual concerned.

SAFEGUARDS:

Files are maintained in file cabinets and other storage devices under the control of authorized personnel during working hours; the office space in which the file cabinets and storage devices are located is locked outside official working hours.

RETENTION AND DISPOSAL:

Records are maintained in the office for four years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Judge Advocate General (Military Justice), Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system contains information about themselves should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, *e.g.,* Armed Forces identification card, driver's license, etc.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Division Director, Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047.

The request should contain full name and address of the individual concerned and should be signed.

Personal visits may be made to the Administrative Support Division, Navy and Marine Corps Appellate Review Activity, Office of the Judge Advocate General, Department of the Navy, 716 Sicard Street SE, Suite 1000, Washington Navy Yard, DC 20374–5047. Individuals making such visits should be able to provide acceptable identification, e.g., Armed Forces identification card, driver's license, etc.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

The records are comprised of the following source materials: (1) Petitions for new trial; (2) forwarding endorsements thereon by petitioner's commanding officer and convening/supervisory authorities of courts-martial (above information is omitted if petitioner is former service member); and (3) action of the Judge Advocate General on petitions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 01–412 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Navy

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Navy proposes to alter a system of records notice in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective on February 7, 2001, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (N09B30), 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545 or DSN 325–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act was submitted on December 19, 2000, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996, (61 FR 6427, February 20, 1996).

Dated: December 21, 2000.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

N05527–1

SYSTEM NAME:

Security Incident System (March 2, 1994, 59 FR 9972).

CHANGES:

System identifier

Delete entry and replace with 'N05580–1'.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add a new paragraph 'To individuals involved in base incidents, their insurance companies, and/or attorneys for the purpose of adjudicating a claim, such as personal injury, traffic accident, or other damage to property. The release of personal information is limited to that required to adjudicate a claim.'

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Maintained for two years and then destroyed.'

* * * * *

N05580–1

SYSTEM NAME:

Security Incident System.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals involved in or witnessing incidents requiring the attention of base, station, or activity security personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Incident/complaint report, investigator's report, data sheets which contain information on victims and perpetrators, military magistrate's records, confinement records, traffic accident and violation records, traffic court file, citations to appear before U.S. Magistrate.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations and E.O. 9397 (SSN).

PURPOSE(S):

To track and prosecute offenses, counsel victims, and other

administrative actions; to support insurance claims and civil litigation; to revoke base, station, or activity driving privileges.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To individuals involved in base incidents, their insurance companies, and/or attorneys for the purpose of adjudicating a claim, such as personal injury, traffic accident, or other damage to property. The release of personal information is limited to that required to adjudicate a claim.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, card files, personal computer, magnetic tape.

RETRIEVABILITY:

Name, Social Security Number, case number, and organization.

SAFEGUARDS:

Access provided on a need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access is controlled by password or other user code system.

RETENTION AND DISPOSAL:

Maintained for two years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Official: Commander, Naval Criminal Investigative Service, Washington Navy Yard, Building 111, 716 Sicard Street SE, Washington Navy Yard, DC 20388–5380.

Record Holder: Commanding Officer of the activity in question. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system contains information about themselves should address written inquiries to the Commanding Officer or head of the activity where assigned. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

Written requests should contain full name, Social Security Number, and must be signed by the individual.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves should address written inquiries to the Commanding Officer or head of the activity where assigned. Official mailing addresses are published as an appendix to the Navy's compilation of systems of records notices.

Written requests should contain full name, Social Security Number, and must be signed by the individual.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE PROCEDURES:

Individual concerned, other records of the activity, investigators, witnesses, and correspondents.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt pursuant to 5 U.S.C. 552a(j)(2) if the information is compiled and maintained by a component of the agency which performs as its principle function any activity pertaining to the enforcement of criminal laws.

An exemption rule for this system has been published in accordance with the requirements of 5 U.S.C. 553(b)(1), (2) and (3), (c) and (e) and published in 32 CFR part 701, subpart G. For additional information contact the system manager.

[FR Doc. 01–417 Filed 1–5–01; 8:45 am]

BILLING CODE 5001–10–U

DEPARTMENT OF EDUCATION

The International Research and Studies Program

AGENCY: Department of Education.

ACTION: Publication of the year 2000 annual report.

SUMMARY: The Secretary announces the publication of the annual report listing the books and research materials produced with assistance provided under Section 605 of the Higher Education Act (HEA), as amended.

SUPPLEMENTARY INFORMATION: Section 605 of the HEA authorizes the International Research and Studies Program. Under this program, the Secretary awards grants and contracts for—

(a) Studies and surveys to determine the needs for increased or improved instruction in modern foreign languages, area studies, or other international fields, including the demand for foreign language, area, and other international specialists in government, education, and the private sector;

(b) Studies and surveys to assess the use of graduates of programs supported under Title VI by governmental, educational, and private sector organizations and other studies assessing the outcomes and effectiveness of programs so supported;

(c) Evaluation of the extent to which programs assisted under Title VI that address national needs would not otherwise be offered;

(d) Comparative studies of the effectiveness of strategies to provide international capabilities at institutions of higher education;

(e) Research on more effective methods of providing instruction and achieving competency in foreign languages, area studies, or other international fields;

(f) The development and publication of specialized materials for use in foreign language, area studies, and other international fields, or for training foreign language, area, and other international specialists;

(g) Studies and surveys of the uses of technology in foreign language, area studies, and international studies programs;

(h) Studies and evaluations of effective practices in the dissemination of international information, materials, research, teaching strategies, and testing techniques throughout the education community, including elementary and secondary schools; and

(i) Research on applying performance tests and standards across all areas of foreign language instruction and classroom use.

2000 Program Activities

In fiscal year 2000, 19 new grants ($1,893,600) and 15 continuation grants ($1,981,400) were awarded under the International Research and Studies Program. These grants are active currently and will be monitored through progress reports submitted by grantees. Grantees have 90 days after the expiration of the grant to submit the products resulting from their research to

the Department of Education for review and acceptance.

Completed Research

A number of completed research projects resulting from grants made during prior fiscal years have been received during the past year. These are listed below.

Title	Author/Location
Yemeni Arabic-English Dictionary	Hamdi A. Qafisheh, Near Eastern Studies, University of Arizona, P.O. Box 210080, Tucson, AZ 85721–0080.
U.S.-Mexico Relations Curriculum Project	Walter Falcon, Institute for International, Studies, C100 Encina Hall, Stanford University, Stanford, CA 94305–6055.
Internet Living Swahili Dictionary	Ann Biersteker, Yale University, Council on African Studies, 155 Whitney Avenue, New Haven, CT 06511.
A National Survey of Foreign Language Instruction in Elementary and Secondary Schools 1995–1998 which contains: The National Survey, A National Directory of Early Foreign Language Programs: Searchable Web Database, and Lessons Learned from Model Early Foreign Language Programs.	Nancy C. Rhodes and Lucinda E. Branaman, Center for Applied Linguistics (CAL), 4646 40th Street, NW, Washington, DC 20016.
Development of Curriculum Materials on China and Japan	Linda K. Menton and Eileen H. Tamura, Curriculum Research and Development Group, University of Hawaii at Manoa, 1776 University Avenue, Honolulu, HI 96822.
SEAsite: A World Wide Web Site for the Languages of Southeast Asia	George M. Henry, Department of Computer Science, Northern Illinois University, Dekalb, IL 60115.
Starfestival Net: An Internet Prototype for International Studies in the Less-Commonly Taught Languages.	Shigeru Miyagawa, Massachusetts Institute of Technology, Department of Foreign Languages and Literatures, 77 Massachusetts Avenue, 14N–305, Cambridge, MA 02139.
Beyond the Oral Proficiency Interview (OPI): The Standards Assessment Design Project: The PAU Project.	Elvira Swender, American Council on the Teaching of Foreign Languages, Inc. (ACTFL), 6 Executive Plaza, Yonkers, NY 10701–6801.
Survey of Foreign Language Registrations in United States Colleges and Universities, Fall 1998 with Comparative Registration Data for 1960, 1968, 1986, 1990 and 1995.	Richard Brod, Modern Language Association of America, 10 Astor Place, New York, NY 10003.
Audio Program for Chinese: Communicating in the Culture	Galal Walker, The Ohio State University, 1960 Kenny Road, Foreign Language Center, Columbus, OH 43210–1063.
Multimedia Chinese Courseware for Classroom And Distance Learning Curriculum.	Ching-I Tu, East Asian Languages and Cultures, Rutgers University, Scott Hall 330, 43 College Avenue, New Brunswick, NJ 08901–1164.

To obtain a copy of a completed study, contact the author at the given address.

FOR FURTHER INFORMATION CONTACT: For a copy of the 2000 annual report and further information regarding the International Research and Studies Program, write to Jose L. Martinez, Program Officer, International Education and Graduate Programs Service, U.S. Department of Education, 1990 K Street, NW., Washington, DC 20006–8521. Telephone: (202) 502–7635.

If you use a telecommunication device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document or the 2000 annual report referred to in this notice in an alternative format (*e.g.* Braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm

http://www.ed.gov/news.html

To use PDF you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at:

http://www.access.gpo.gov/nara/index.html

Program Authority: 20 U.S.C. 1125.

Dated: January 3, 2001.

A. Lee Fritschler,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 01–461 Filed 1–5–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Notice of Availability of the Draft Site-Wide Environmental Impact Statement for the Oak Ridge Y–12 Plant

AGENCY: Energy, National Nuclear Security Administration, DOE.

ACTION: Notice of availability and public hearings

SUMMARY: The National Nuclear Security Administration (NNSA), a semi-autonomous agency within the Department of Energy (DOE), announces the availability of the Draft Site-Wide Environmental Impact Statement for the Oak Ridge Y–12 Plant [Y–12 Draft SWEIS] (DOE/EIS–0309), and the dates and locations for public hearings to receive comments on the Y–12 Draft SWEIS. The Y–12 Draft SWEIS evaluates the potential environmental impacts associated with the continued operations of the Y–12 Plant, as well as with alternatives for modernizing Y–12 facilities to ensure its capability to meet future nuclear weapon stockpile needs in the post-Cold War era. The alternatives include construction and operation of new facilities for two of Y–12's missions: Highly Enriched Uranium

(HEU) Materials Storage mission and Special Materials mission. The preferred alternative is to construct and operate a new HEU Materials Storage Facility and a new Special Materials Complex. Preferred sites on Y–12 for these new facilities have not been selected, but will be identified in the Y–12 Final SWEIS.

DATES: Comments on the Y–12 Draft SWEIS may be submitted to DOE (see Addresses below) until February 5, 2001. To ensure consideration in the Y–12 Final SWEIS, comments must be postmarked by February 5, 2001. Late comments will be considered to the extent practicable. Two public hearings to discuss issues and receive oral comments on the Y–12 Draft SWEIS will be held as follows: Thursday, January 25, 2001, in the Cumberland Room at the Oak Ridge Conference Center located at the Oak Ridge Mall, Oak Ridge, Tennessee. The first hearing will be held from 1–4 p.m. The second public hearing will be held from 6–9 p.m. The public hearings will provide the public with an opportunity to present comments, ask questions, and discuss concerns with DOE/NNSA officials regarding the Y–12 Draft SWEIS.

ADDRESSES: Comments on the Y–12 Draft SWEIS may be submitted by mail (U.S. Department of Energy, Oak Ridge Operations Office, Attn: Mr. Gary Hartman, P.O. Box 2001, Oak Ridge, TN 37831), by fax (1–865–576–1237), by phone (1–865–576–0273), or electronically (*Y12EIS@oro.doe.gov*). Specific information regarding the public meetings can be obtained by calling 1–865–576–0273, writing to the address above, or electronically via the Y–12 SWEIS web site: *http://www.ttclients.com/y12/*. Copies of the Y–12 Draft SWEIS and/or its Summary may also be obtained by contacting Mr. Gary Hartman by any of the means described above. The Y–12 Draft SWEIS is also available for review at the U.S. Department of Energy Public Reading Room at 230 Warehouse Road, Oak Ridge, TN 37830.

FOR FURTHER INFORMATION CONTACT: For general information on the NNSA NEPA process, please contact: Mr. Henry Garson, NEPA Compliance Officer for Defense Programs, U.S. Department of Energy/NNSA, 1000 Independence Avenue, SW., Washington, DC 20585; or telephone 1–800–832–0885, ext. 30470. For general information on the DOE NEPA process, please contact: Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (EH–42), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, telephone 202–586–4600, or leave a message at 1–800–472–2756.

SUPPLEMENTARY INFORMATION: The NNSA is responsible for providing the Nation with nuclear weapons and ensuring that those nuclear weapons remain safe, secure, and reliable. As one of the major production facilities, the Oak Ridge Y–12 Plant has been DOE's primary site for enriched uranium processing and storage, and one of the manufacturing facilities for maintaining the U.S. nuclear weapons stockpile. In recent years, the emphasis of the U.S. weapons program has shifted from developing and producing new weapons to dismantlement and maintenance of a smaller stockpile.

The Y–12 Draft SWEIS evaluates the potential environmental impacts from continued operation of the Oak Ridge Y–12 Plant, and the construction and operation of new facilities for two of Y–12's missions: HEU Materials Storage mission and Special Materials mission. Alternatives considered for the HEU Materials Storage mission include constructing and operating a new HEU Materials Facility at one of two candidate sites, or expanding and operating Building 9215. Three candidate sites are evaluated for a new Special Materials Complex for the Special Materials mission at Y–12. More specifically, the Y–12 Draft SWEIS analyzes potential impacts on land uses, transportation, socioeconomics, geology and soils, hydrology, biological resources, air quality/noise, site facilities and support activities, waste management, and cultural resources. In addition, environmental justice, radiological and chemical impacts during normal operations, and effects of accidents on workers and the public are included in the assessment. A disclaimer statement was mistakenly printed on the inside cover of each volume of the Draft SWEIS. DOE wishes to inform the public that the information contained in the Draft SWEIS is accurate and complete. Please disregard this disclaimer statement.

The preferred alternative is to construct and operate a new HEU Materials Storage Facility and a new Special Materials Complex. Preferred sites on Y–12 for these new facilities have not been selected, but will be identified in the Y–12 Final SWEIS. The Y–12 Final SWEIS is scheduled to be completed in August 2001. A Record of Decision would be issued no sooner than 30 days after the Y–12 Final SWEIS is issued.

Issued in Washington, DC this 29th day of December, 2000.

Madelyn R. Creedon,

Deputy Administrator for Defense Programs, National Nuclear Security Administration, Department of Energy.

[FR Doc. 01–443 Filed 1–5–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

PhA Environmental Restoration Corporation

AGENCY: Office of the General Counsel, DOE.

ACTION: Notice of intent to grant exclusive patent licenses.

SUMMARY: Notice is hereby given of an intent to grant to PhA Environmental Restoration Corp., of Oak Hill, Virginia, exclusive licenses to practice the inventions described in U.S. Patent No. 5,324,661, entitled ''Chemotactic Selection of Pollutant Degrading Bacteria'' and U.S. Patent No. 5,326,703, entitled ''Method of Degrading Pollutants in Soil.'' The inventions are owned by the United States of America, as represented by the U.S. Department of Energy (DOE).

DATES: Written comments or nonexclusive license applications are to be received at the address listed below no later than March 9, 2001.

ADDRESSES: Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Robert J. Marchick, Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, Forrestal Building, Room 6F–067, 1000 Independence Avenue, SW., Washington, DC 20585; Telephone (202) 586–4792.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 209 provides the Department with authority to grant exclusive licenses in Department-owned inventions, if, among other things, the agency finds that the public will be served by the granting of the license. The statute requires that no exclusive license may be granted unless public notice of the intent to grant the license has been provided, and the agency has considered all comments received, in response to that public notice, before the end of the comment period.

PhA Environmental Restoration Corporation, of Oak Hill, Virginia, has applied for exclusive license to practice

the inventions embodied in U.S. Patent Nos. 5,324,661 and 5,326,703, and has plans for commercialization of the inventions.

The exclusive licenses will each be subject to a license and other rights retained by the U.S. Government, and other terms and conditions to be negotiated. DOE intends to negotiate to grant the licenses, unless, within 60 days of this notice, the Assistant General Counsel for Technology Transfer and Intellectual Property, Department of Energy, Washington, DC 20585, receives in writing any of the following, together with supporting documents:

(i) A statement from any person setting forth reasons why it would not be in the best interests of the United States to grant either of the proposed licenses; or

(ii) An application for a nonexclusive license to either invention, in which applicant states that he already has brought either invention to practical application or is likely to bring either invention to practical application expeditiously.

The Department will review all timely written responses to this notice, and will proceed with negotiating the licenses if, after consideration of written responses to this notice, a finding is made that the licenses are in the public interest.

Issued in Washington, DC, on January 2, 2001.

Paul A. Gottlieb,

Assistant General Counsel for Technology, Transfer and Intellectual Property.

[FR Doc. 01–441 Filed 1–5–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Umatilla Generating Project

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: This notice announces BPA's intention to prepare an EIS, under the National Environmental Policy Act (NEPA), on a proposed electrical interconnection requested by Umatilla Generating Company, L.P., to integrate electrical power from the Umatilla Generating Project into the Federal transmission grid. BPA proposes to execute an agreement with Umatilla Generating Company L.P., to provide them with an interconnection.

DATES: BPA has established a 45-day scoping period during which affected landowners, concerned citizens, special interest groups, local governments, and any other interested parties are invited to comment on the scope of the proposed EIS. Written comments are due to the address below no later than February 22, 2001. Comments may also be made at an EIS scoping open house meeting to be held on January 30, 2001.

ADDRESSES: To comment, telephone toll-free 1–800–622–4519; send an e-mail to the BPA Internet address *comment@bpa.gov;* or mail comments to Communications, Bonneville Power Administration—KC–7, P.O. Box 12999, Portland, Oregon, 97212. To be placed on the project mail list, call 1–800–622–4520.

An EIS open house will be held on January 30, 2001, 7:00 p.m. to 9:00 p.m., at Hermiston High School, 600 S. First Street, Hermiston, Oregon. At this informal scoping meeting, BPA staff will answer questions and accept oral and written comments, and representatives of BPA and the Umatilla Generating Company, L.P., will be available to discuss the proposed project and the topics to be addressed in the EIS. Information on the proposed project will be available for review.

Scoping will help BPA ensure that a full range of issues related to this proposal is addressed in the EIS, and also will identify significant or potentially significant impacts that may result from the proposed project. When completed, the Draft EIS will be circulated for review and comment, and BPA will hold a public comment meeting on the Draft EIS. BPA will consider and respond in the Final EIS to comments received on the Draft EIS.

FOR FURTHER INFORMATION CONTACT: Thomas C. McKinney, Bonneville Power Administration—KEC–4, P.O. Box 3621, Portland, Oregon, 97208–3621; toll-free telephone 1–800–282–3713; direct telephone 503–230–4749; or e-mail *tcmckinney@bpa.gov.* Additional information can be found at BPA's web site: *www.bpa.gov.*

SUPPLEMENTARY INFORMATION: The EIS will assess the environmental consequences of the agreement which BPA proposes with Umatilla Generating Company, L.P., and of any modifications to the transmission system needed to provide an electrical connection under the terms of the agreement. In addition to these Federal actions, the EIS will consider the environmental consequences of construction and operation of the Umatilla Generating Project.

The proposed project has several components. They include an electrical connection at BPA's McNary Substation for the Umatilla Generating Company, L.P.; a natural-gas-fired, combined-cycle combustion turbine; electric-power-generation plant (Umatilla Generating Project); a natural-gas pipeline; and new and modified electric-power-transmission lines. All proposed facilities would be located within Umatilla County, Oregon.

The Umatilla Generating Project is proposed by the Umatilla Generating Company, L.P., an independent power producer. They would build and operate the power plant, and would also pay for the construction of approximately three-quarters of a mile of new transmission lines and modification of approximately 11 miles of existing transmission lines owned by the Umatilla Electric Cooperative. The new transmission lines would be owned by the Umatilla Electric Cooperative. PG&E Gas Transmission-Northwest Corporation (GTN) or Cascade Natural Gas would build a natural-gas pipeline up to 5 miles in length to supply fuel to the power plant.

A. Proposed Action. The proposed Umatilla Generating Project would be a combustion turbine/combined-cycle electric power plant with a nominal generating capacity of 550 megawatts. The energy facility site would be located about 4 miles southwest of the city of Hermiston and about one-half mile west of the existing Hermiston Generating Plant.

The proposed Umatilla Generating Project would consist of two essentially identical combustion turbine generators, two heat-recovery steam generators (HRSG) and one steam turbine. The proposed generating project would be fueled by natural gas from the existing GTN pipeline that passes approximately 5 miles south of the energy facility site. Natural gas would be burned in the combustion turbines. Expanding gases from combustion would turn rotors within the turbines that are connected to electric generators. The hot gases exhausted from the combustion turbines would be used to raise steam in the HRSGs. Steam from the HRSGs would be expanded through a steam turbine that drives its own electric generator.

Water would be needed at the facility to generate steam and cool the steam process. Water would be supplied from the Port of Umatilla's regional water supply pipeline that currently extends to the Hermiston Generating Plant. A recirculating cooling system employing mechanically induced draft evaporative cooling towers would be used to minimize water use. Water would be

added to the cooling system to compensate for evaporative losses (make-up water) and blowdown. Blowdown is the water bled from the cooling system to limit the build-up of salts. Blowdown would be conveyed by pipeline to Madison Farms, located approximately 3 miles south of the proposed generating project, where it would be applied to crops.

The proposed Umatilla Generating Project would deliver electric power to the regional power grid at BPA's McNary Substation in Umatilla using the Umatilla Electric Cooperative's existing Westland-McNary Transmission Line. A new 230-kilovolt (kV) radial transmission line tap would be constructed to connect the switchyard at the proposed Umatilla Generating Project to the Westland-McNary Transmission Line. Presently, the transmission line consists of one 115-kV circuit and one 230-kV circuit. The existing 115-kV line would be removed and replaced with a 230-kV line. BPA would modify the McNary Substation to accept electric power from the Umatilla Generating Project.

In addition, the section of the 115–kV transmission line between the Umatilla Generating Project and the Hermiston Generating Plant would be reconductored for 230 kV. This portion of the circuit reconductoring would increase the overall efficiency and reliability of the transmission line.

B. Process to Date. BPA is the lead Federal agency for the project EIS. The State of Oregon Energy Facility Siting Council is currently evaluating the Application for a Site Certificate for the Umatilla Generating Project submitted by the Umatilla Generating Company, L.P. Oregon's site evaluation process, like NEPA, provides opportunity for public participation. Umatilla Generating Company, L.P., held a public informational meeting on December 7, 2000. Umatilla Generating Company, L.P., expects to submit an application for Air Contaminant Discharge and Prevention of Significant Deterioration Permit for the proposed project to the Oregon Department of Environmental Quality in January 2001.

C. Alternatives Proposed for Consideration. Alternatives thus far identified for evaluation in the EIS are: (1) The proposed action, and (2) no action. Other alternatives may be identified through the scoping process.

D. Identification of Environmental Issues. BPA intends to prepare an EIS addressing both the Umatilla Generating Project and the associated electric power interconnection facilities. BPA decided to prepare the EIS for two reasons: (1) The Umatilla Generating Project would depend on the modifications at BPA's McNary Substation to connect with BPA's transmission grid, and (2) no other Federal or State agency is currently preparing an EIS on the proposed project. Because no other EIS is being prepared, the scope of BPA's EIS will cover both the interconnection elements and the Umatilla Generating Project.

The principal issues identified thus far for consideration in the Draft EIS with respect to the Umatilla Generating Project are as follows: (1) Air quality impacts, (2) noise impacts from plant operation, (3) aesthetic impacts, (4) socioeconomic impacts created by an influx of construction workers into a sparsely populated area, and (5) impacts on wildlife habitat. The principal issues identified thus far for consideration in the Draft EIS with respect to the electric power transmission facilities are as follows: (1) Impacts of transmission line construction on wetlands and wildlife habitat, (2) aesthetic impacts, and (3) cultural resource impacts.

These issues, together with any additional significant issues identified through the scoping process, will be addressed in the EIS.

Issued in Portland, Oregon, on December 27, 2000.

Stephen J. Wright,

Acting Administrator and Chief Executive Officer.

[FR Doc. 01–442 Filed 1–5–01; 8:45 am]

BILLING CODE 6450–01–U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–627–001, et al.]

Commonwealth Edison Company, et al.; Electric Rate and Corporate Regulation Filings

January 2, 2001.

Take notice that the following filings have been made with the Commission:

1. Commonwealth Edison Company

[Docket No. ER01–627–001]

Take notice that on December 21, 2000, Exelon Corporation (Exelon), on behalf of its subsidiaries, Commonwealth Edison Company (ComEd) and Exelon Generation, L.L.C. (Exelon Generation), tendered for filing an amendment to its December 8, 2000, filing of a form of agreement entitled Ancillary and Other Control Area Services Resource Purchase Agreement (hereafter the Agreement). Due to an administrative oversight, the Agreement references various Schedules which were inadvertently omitted in Exelon's December 8, 2000 filing. Per an informal request of FERC Staff, ComEd is accordingly submitting with this transmittal letter the Agreement, along with the previously omitted Schedules referenced in said Agreement.

FERC Staff has advised ComEd that making this amended filing should not affect the effective date of January 1, 2001 requested by ComEd in its December 8, 2000 filing in this docket.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. Commonwealth Edison Company

[Docket No. ER01–628–001]

Take notice that on December 21, 2000, Commonwealth Edison Company (ComEd) tendered for filing an amendment to its December 8, 2000, filing to revise Schedules 4, 4A and 4G to ComEd's Open Access Transmission Tariff (OATT). Second Revised Sheet No. 124 of ComEd's OATT references Schedule 1 of the Ancillary and Other Control Area Services Resource Purchase Agreement (Agreement) between ComEd and Exelon Generation, L.L.C., filed contemporaneously in Docket No. ER01–627–000 with the revisions to Schedules 4, 4A and 4G. Per an informal request of FERC Staff, ComEd is amending its filing to include Schedule 1 of the Agreement as Attachment A to Schedule 4, instead of merely referencing it in Schedule 4 to ComEd's OATT.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. Southwestern Electric Power Company

[Docket No. ER01–651–001]

Take notice that on December 21, 2000, Southwestern Electric Power Company (SWEPCO) tendered for filing in this subdocket rate sheets reflecting a proposed fixed return on common equity (ROE) to be used in establishing estimated and final redetermined formula rates for wholesale service to the City of Bentonville, Arkansas (Bentonville). SWEPCO currently provides service to Bentonville and its other wholesale formula rate customers under contracts which provide for periodic changes in rates and charges determined in accordance with cost-of-service formulas, including a formulaic determination of the ROE. SWEPCO has proposed in this docket to replace the formulaic ROE with a fixed ROE. The filing in this subdocket is solely to file the proposed Bentonville rate sheets

that have been conformed to Order No. 614.

SWEPCO seeks an effective date of January 1, 2001 and, accordingly, seeks waiver of the Commission's notice requirements. Copies of the filing were served on Bentonville, all parties to this proceeding and the Arkansas Public Service Commission.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. Tampa Electric Company

[Docket No. ER01–713–001]

Take notice that on December 21, 2000, Tampa Electric Company (Tampa Electric) tendered for filing a service agreement with Enron Power Marketing, Inc. (Enron) under Tampa Electric's market-based sales tariff. Tampa Electric submitted an amended service agreement designation on December 21, 2000.

Tampa Electric proposes that the service agreement be made effective on December 1, 2000, and gives notice of its termination as of January 1, 2001.

Copies of the filing have been served on Enron and the Florida Public Service Commission.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Illinois Power Company

[Docket No. ER01–740–000]

Take notice that on December 21, 2000, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 65251–2200, filed with the Commission a Service Agreement for Firm Short-Term Point-To-Point Transmission Service with Wisconsin Public Service Corporation (WPS) entered into pursuant to Illinois Power's Open Access Transmission Tariff. Also on December 22, 2000, Illinois Power filed a letter clarifying a statement in its request for waiver filed with the above-mentioned Service Agreement.

Illinois Power requests an effective date of November 9, 2000 for the Agreement and accordingly seeks a waiver of the Commission's notice requirement based on extraordinary circumstances.

Illinois Power has served a copy of the filing on WPS.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. California Independent System Operator Corporation

[Docket No. ER01–724–000]

Take notice that on December 21, 2000, the California Independent System Operator Corporation (ISO), tendered for filing a revision to the Transmission Control Agreement (TCA) for acceptance by the Commission. The ISO states that the purpose of the amendment is (1) to clarify responsibilities in the TCA concerning the ISO Maintenance Standards and to include a new Appendix F identifying the persons to contact at each party for notice purposes; (2) to address the Commission's statement in Mid-Continent Area Power Pool, 92 FERC ¶ 61,229 that contractual arrangements involving regional transmission service should be crafted to ensure that responsibilities of all parties with respect to issues such as refunds are delineated in advance; (3) to clarify four provisions of the current TCA in response to issues raised by the City of Vernon, California (Vernon), which has applied to become a Participating Transmission Owner; and (4) to identify the transmission interests that Vernon would be turning over to the ISO's Operational Control if Vernon executes the amended TCA unconditionally.

The ISO states that this filing has been served the Public Utilities Commission of California, the California Energy Commission, the California Electricity Oversight Board, and all parties, including Vernon, with effective Scheduling Coordinator Agreements under the ISO Tariff.

The ISO is requesting waiver of the 60-day notice requirement to allow the TCA to be made effective January 1, 2001.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Wisconsin Electric Power Company

[Docket No. ER01–252–001]

Take notice that on December 21, 2000, Wisconsin Electric Power Company (Wisconsin Electric) submitted a filing containing designations pursuant to Order No. 614, in compliance with the letter order issued December 11, 2000 in Docket No. ER01–252–000 in which the Commission accepted the filing, effective January 1, 2001.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Citizens Communications Company

[Docket No. ER01–249–001]

Take notice that on December 21, 2000, in compliance with the Commission's December 6, 2000 letter order in this proceeding, Citizens Communications Company filed on a non-confidential basis an Agreement to sell to Select Energy, Inc. a portion of its energy entitlement pursuant to the Firm Energy Contract between NEPOOL Phase II Participants and HydroQuebec, dated October 4, 1984.

A copy of this filing was served on the service list in this docket, and on Select Energy, Inc. In addition, a copy of the rate schedule is available for inspection at the offices of Citizens' Vermont Electric Division during regular business hours.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. FirstEnergy Operating Companies

[Docket No. ER00–3771–002]

Take notice that on December 21, 2000, The Cleveland Electric Illuminating Company, Ohio Edison Company, Pennsylvania Power Company and The Toledo Edison Company (collectively, the FirstEnergy Operating Companies) tendered for filing their FERC Electric Tariff, First Revised Volume No. 3, pursuant to which they are offering to make available ancillary services and interconnected operations services. The FirstEnergy Operating Companies state that this tariff contains modifications to a tariff submitted in September 2000 that were required by the Order Accepting for Filing, as Modified, Proposed Tariff and Service Agreement which was issued in this proceeding on November 22, 2000.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. New England Power Pool

[Docket No. ER00–3577–003]

Take notice that on December 22, 2000, the New England Power Pool (NEPOOL) Participants Committee and ISO New England Inc. submitted a joint report of compliance in response to requirements of the Commission's November 22, 2000 order in Docket No. ER00–3577–000. New England Power Pool, 93 FERC ¶ 61,195 (2000).

The NEPOOL Participants Committee states that copies of these materials were sent to all persons identified on the service list in the captioned proceeding, the NEPOOL Participants and the six New England state governors and regulatory commissions.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Sithe Edgar LLC; Sithe New Boston LLC; Sithe Framingham LLC; Sithe West Medway LLC; Sithe Wyman LLC; Sithe Mystic LLC; AG-Energy, L.P.; Power City Partners, L.P.; Seneca Power Partners, L.P.; Sterling Power Partners, L.P.; Sithe Power Marketing, L.P.; Sithe Power Marketing, Inc.

[Docket No. ER00–3691–001]

Take notice that on December 21, 2000, the above referenced applicants (the Sithe Jurisdictional Affiliates) filed with the Commission proposed rate schedule designations in compliance with Order No. 614, and the Order issued in this proceeding on November 24, 2000.

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Commonwealth Edison Company

[Docket Nos. ER00–2814–003]

Take notice that on December 21, 2000, Commonwealth Edison Company (ComEd) submitted for filing an executed Dynamic Scheduling Agreement (Agreement) with its Wholesale Merchant Function Division (WMD) under ComEd's Open Access Transmission Tariff (OATT) in compliance with the Commission's December 14, 2000 Order issued in Docket Nos. ER00–2814–000, ER00–2814–001, and ER00–2814–002. *Commonwealth Edison Company,* 93 FERC & 61,271 (2000).

Comment date: January 11, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. UtiliCorp United Inc.

[Docket No. ER99–203–002]

Take notice that on December 22, 2000, UtiliCorp United Inc. filed the required three-year updated market analysis in this docket.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Bangor Energy Resale, Inc.

[Docket No. ER98–459–009]

Take notice that on December 22, 2000, Bangor Energy Resale, Inc. (Bangor Energy) filed an updated market analysis as required by the Commission's December 23, 1997 order in Docket No. ER98–459–000 granting Bangor Energy market based rate authority.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. Wolverine Power Supply Cooperative, Inc.

[Docket No. ER98–411–010]

Take notice that on December 22, 2000, Wolverine Power Supply Cooperative, Inc. (Wolverine), filed a revised Generation Market Dominance Analysis, in compliance with the Commission's Order in Wolverine Power Supply Cooperative, Inc., 81 FERC ¶ 61,369 (1997).

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Dynegy Roseton, L.L.C.

[Docket No. EG01–80–000]

Take notice that on December 21, 2000, Dynegy Roseton, L.L.C., 1000 Louisiana, Suite 5800, Houston, Texas filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Dynegy Roseton, L.L.C. is a Delaware limited liability company, and is engaged directly and exclusively in owning and/or operating an electric generating facility in New York, and selling electric energy at wholesale.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

17. Harquahala Generating Company, LLC

[Docket No. EG01–81–000]

Take notice that on December 21, 2000, Harquahala Generating Company, LLC (Harquahala), a limited liability company with its principal place of business at 7500 Old Georgetown Road, Bethesda, Maryland 20814, filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

Harquahala proposes to construct, own or lease and operate a natural gas-fired, combined cycle power plant of approximately 1050 MW capacity in Maricopa County, Arizona. The proposed power plant is expected to commence commercial operation in 2003. All output from the plant will be sold by Harquahala exclusively at wholesale.

Comment date: January 22, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

18. Dynegy Danskammer, L.L.C.

[Docket No. EG01–82–000]

Take notice that on December 21, 2000, Dynegy Danskammer, L.L.C., 1000 Louisiana, Suite 5800, Houston, Texas filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's Regulations.

Dynegy Danskammer, L.L.C. is a Delaware limited liability company, and is engaged directly and exclusively in owning and/or operating an electric generating facility in New York, and selling electric energy at wholesale.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. 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 motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–439 Filed 1–5–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–739–000, et al.]

Duke Electric Transmission, et al.; Electric Rate and Corporate Regulation Filings

December 29, 2000.

Take notice that the following filings have been made with the Commission:

1. Duke Electric Transmission, a Division of Duke Energy Corporation

[Docket No. ER01–739–000]

Take notice that on December 21, 2000, Duke Electric Transmission (Duke ET), tendered for filing First Revised Service Agreement No. 194 with Carolina Power & Light Company, for Transmission Service under Duke ET's Open Access Transmission Tariff.

Duke requests that the proposed Revised Service Agreement be permitted to become effective on January 1, 2001.

Duke states that this filing is in accordance with Part 35 of the Commission's Regulations and a copy has been served on the North Carolina Utilities Commission.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. Puget Sound Energy, Inc.

[Docket No. ER01–743–000]

Take notice that on December 21, 2000, Puget Sound Energy, Inc., as Transmission Provider, tendered for filing a Service Agreement for Firm Point-To-Point Transmission Service and a Service Agreement for Non-Firm Point-To-Point Transmission Service with The Legacy Energy Group, LLC (Legacy) as Transmission Customer.

A copy of the filing was served upon Legacy.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. Puget Sound Energy, Inc.

[Docket No. ER01–744–000]

Take notice that on December 21, 2000, Puget Sound Energy, Inc., as Transmission Provider, tendered for filing a Service Agreement for Firm Point-To-Point Transmission Service and a Service Agreement for Non-Firm Point-To-Point Transmission Service with El Paso Merchant Energy, L.P. (EPME), as Transmission Customer.

A copy of the filing was served upon EPME.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. New England Power Company

[Docket No. ER01–745–000]

Take notice that on December 21, 2000, New England Power Company (NEP) tendered for filing a service agreement between NEP and Rhode Island State Energy Partners, L.P. (RISEP) for Firm Local Generation Delivery Service under NEP's FERC Electric Tariff, Original Volume No. 9.

Copies of the filing have been served upon RISEP and the Rhode Island Public Utilities Commission.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Consumers Energy Company

[Docket No. ER01–746–000]

Take notice that on December 21, 2000, Consumers Energy Company (Consumers), tendered for filing a Facilities Agreement Between Consumers and Wolverine Power Supply Cooperative, Inc, (Wolverine), dated November 30, 2000 (Agreement). Under the Agreement, Consumers is to build, operate and maintain certain facilities interconnecting Wolverine's Vestaburg substation and Consumers' transmission system.

Consumers requested that the Agreement be allowed to become effective October 23, 1998.

Copies of the filing were served upon Wolverine and the Michigan Public Service Commission.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Attala Generating Company, LLC

[Docket No. ER01–747–000]

Take notice that on December 21, 2000, Attala Generating Company, LLC (Attala), tendered for filing pursuant to Section 205 of the Federal Power Act, and Part 35 of the Commission's Regulations, an application for authorization to make sales of capacity, energy, and certain Ancillary Services at market-based rates; to reassign transmission capacity; and to resell firm transmission rights (FTRs). Attala proposes to own or lease and operate a natural gas-fired, combined cycle power plant of approximately 500 MW capacity in Attala County, Mississippi.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Harquahala Generating Company, LLC

[Docket No. ER01–748–000]

Take notice that on December 21, 2000, Harquahala Generating Company, LLC (Harquahala), tendered for filing, pursuant to Section 205 of the Federal Power Act, and Part 35 of the Commission's Regulations, an application for authorization to make sales of capacity, energy, and certain Ancillary Services at market-based rates; to reassign transmission capacity; and to resell firm transmission rights (FTRs). Harquahala proposes to construct a natural gas-fired, combined cycle power plant of approximately 1,050 MW capacity in Maricopa County near the town of Tonopah, Arizona.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Ameren Services Company

[Docket No. ER01–749–000]

Take notice that on December 21, 2000, Ameren Services Company (ASC), tendered for filing a Service Agreement for Firm Point-to-Point Transmission Services between ASC and Ameren Energy, Inc., (customer). ASC asserts that the purpose of the Agreement is to permit ASC to provide transmission service to customer pursuant to Ameren's Open Access Transmission Tariff.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. WPS Resources Operating Companies

[Docket No. ER01–750–000]

Take notice that on December 21, 2000, WPS Resources Operating Companies (WPSR), tendered for filing a revised executed service agreement with Stratford Water & Electric Utility (Stratford) for ancillary services and distribution service under WPSR's open access transmission tariff, FERC Electric Tariff, Original Volume No. 1 (OATT).

WPSR requests a January 1, 2001 effective date.

Copies of the filing were served upon Stratford, the Michigan Public Service Commission and the Public Service Commission of Wisconsin.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Mountain View Power Partners, LLC

[Docket No. ER01–751–000]

Take notice that on December 21, 2000, Mountain View Power Partners, LLC (Mountain View) tendered for filing with Commission an application for acceptance of Mountain View's Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electric energy, capacity and ancillary services at market-based rates; and the waiver of certain Commission regulations.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. PJM Interconnection, L.L.C.

[Docket No. ER01–752–000]

Take notice that on December 21, 2000, PJM Interconnection, L.L.C. (PJM),

tendered for filing the following revisions to PJM's Open Access Transmission Tariff (Tariff):

Third Revised Sheet No. 24
Third Revised Sheet No. 72
Original Sheet No. 87V

and the following revisions to the Amended and Restated Operating Agreement of PJM Interconnection, L.L.C. (OA):

First Revised Sheet No. 42

PJM states that the Tariff and OA revisions are related to the restructuring of the Mid-Atlantic Area Council, which is the reliability council for the PJM region.

PJM requests an effective date of January 1, 2001 for the tariff and OA revisions.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Enron Power Marketing, Inc.; Enron Energy Services, Inc.; Clinton Energy Management Services, Inc.; New Albany Power I, L.L.C.; Enron Energy Marketing Corp.; The New Power Company

[Docket No. ER01–753–000]

Take notice that on December 21, 2000, the above listed marketing affiliates of Enron Corp., tendered for filing proposed changes in their respective Rate Schedule FERC No. 1 and the proposed elimination of Codes of Conduct. The changes consist of removing restrictions on the sale of power and non-power goods and services between the listed Enron Marketing Affiliates and Portland General Electric Company (PGE), based on Enron Corp.'s pending sale of PGE. That sale would cause the above-listed Enron Marketing Affiliates no longer to be affiliated with PGE.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Tucson Electric Power Company

[Docket No. ER01–754–000]

Take notice that on December 21, 2000, Tucson Electric Power Company tendered for filing one (1) umbrella service agreement (for short-term firm service) and one (1) service agreement (for non-firm service) pursuant to Part II of Tucson's Open Access Transmission Tariff, which was filed in Docket No. ER00–771–000.

The details of the service agreements are as follows:

(1) Umbrella Agreement for Short-Term Firm Point-to-Point Transmission Service dated as of November 30, 2000 by and between Tucson Electric Power Company and Tri-State G&T Power Marketing—FERC Electric Tariff Vol. No. 2, Service Agreement No. 144. No service has commenced at this time.

(2) Form of Service Agreement for Non-Firm Point-to Point Transmission Service dated as of November 30, 2000 by and between Tucson Electric Power Company and Tri-State G&T Power Marketing—FERC Electric Tariff Vol. No. 2, Service Agreement No. 145. No service has commenced at this time.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Public Service Company of New Mexico

[Docket No. ER01–755–000]

Take notice that on December 21, 2000, Public Service Company of New Mexico (PNM), tendered for filing a revised service agreement (dated August 4, 2000), for electric power and energy sales at negotiated rates under the terms of PNM's Power and Energy Sales Tariff, with American Electric Power Service Corporation. PNM's filing is available for public inspection at its offices in Albuquerque, New Mexico.

Copies of the filing have been sent to American Electric Power Services Corporation and to the New Mexico Public Regulation Commission.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. PJM Interconnection, L.L.C.

[Docket No. ER01–756–000]

Take notice that on December 21, 2000, PJM Interconnection, L.L.C. (PJM), tendered for filing an executed interconnection service agreement between PJM and Bethlehem Steel Corporation.

PJM requests a waiver of the Commission's 60-day notice requirement to permit the effective dates agreed to by the parties.

Copies of this filing were served upon Bethlehem Steel Corporation and the state electric utility regulatory commissions within the PJM control area.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Wayne-White Counties Electric Cooperative

[Docket No. ER01–757–000]

Take notice that on December 21, 2000, Wayne-White Counties Electric Cooperative (WWCEC or Cooperative), tendered for filing an executed Service Agreement for Firm Point-to-Point Transmission Service with Illinois Power Company. Under the Service Agreement, WWCEC will provide firm point-to-point transmission service to Illinois Power Company under the Cooperative's Open Access Transmission Tariff.

WWCEC requests an effective date of January 1, 2001, the date service will be first provided.

A copy of the filing was served upon Illinois Power Company.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. West Texas Utilities Company

[Docket No. ER01–758–000]

Take notice that on December 21, 2000, West Texas Utilities Company (WTU), tendered for filing a revised service agreement (Service Agreement) under WTU's Wholesale Power Choice Tariff (WPC Tariff) between WTU and Pedernales Electric Cooperative, Inc., (Pedernales). WTU states that the Service Agreement originally was between WTU and Kimble Electric Cooperative, Inc. (Kimble) and that, on July 14, 2000, Kimble transferred all right, title and interest in the service agreement to Pedernales. The only change to the Service Agreement is the change in names.

WTU requests an effective date for the revised service agreement of July 14, 2000. Accordingly, WTU requests waiver of the Commission's notice requirements.

WTU states that a copy of the filing was served on Pedernales and on the Public Utility Commission of Texas.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Connecticut Yankee Atomic Power Company

[Docket No. ER01–813–000]

Take notice that on December 21, 2000, Connecticut Yankee Atomic Power Company (Connecticut Yankee), tendered for filing a limited general policy compliance filing proposing to change the application of certain funds collected for post-retirement benefits other than pensions (PBOP) into the external nonqualified nuclear decommissioning trust fund until such time as they are needed to meet PBOP obligations. Connecticut Yankee states that the proposed change would have no impact on its revenue requirement.

Connecticut Yankee states that copies of the filing have been provided to its jurisdictional customers and to state regulatory authorities in Vermont, New Hampshire, Maine, Massachusetts, Connecticut and Rhode Island.

Comment date: January 12, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. Southern California Water Company, d/b/a Bear Valley Electric Service, Complainant, v. Southern California Edison Company, Respondent.

[Docket No. EL01–25–000]

Take notice that on December 28, 2000, Southern California Water Company, d/b/a Bear Valley Electric Service, tendered for filing a complaint against Southern California Edison Company alleging that Edison was seeking unlawfully to terminate the Added Facilities Agreement between the parties, Southern California Edison FERC Electric Rate Schedule No. 394.4.

Comment date: January 18, 2001, in accordance with Standard Paragraph E at the end of this notice. Answers to the complaint shall also be due on or before January 18, 2001.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. 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 motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–438 Filed 1–5–01; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6927–8]

Financial Assistance for an Environmental Professional Intern Program

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (US EPA) announces the availability of Federal Assistance to conduct an intern program to provide on the job training for students interested in careers in environmental protection. The need for wise stewardship of the nation's environmental resources is increasing and with it a need to enlarge the pool of skilled environmental professionals and at the same time increase the diversity of this pool. EPA recognizes that there is a shortage of skilled environmental professionals. The programmatic objective of this intern program is to provide unique opportunities for cooperative study, research, and development that would increase the number and diversity of skilled engineers, scientists, policy makers, legal professionals, and managers in the environmental arena by affording ''on the job training'' opportunities for students interested in public or private sector careers in environmental protection.

This solicitation is to find a qualified non-profit organization to carry out this student intern program. The student interns will be considered employees of the cooperative partner rather than EPA during their training period. All student interns must be enrolled in an undergraduate or graduate program, or accepted into an undergraduate or graduate program that will commence within nine months of selection as a student intern. This partner would be responsible for locating candidate interns, selecting the interns and administering the funding to the Interns/Associates. USEPA would identify the intern/associate opportunities at EPA or EPA stakeholder facilities, provide advice to the cooperative partner in the selection of the candidate interns and provide space, technical guidance and training to the Interns/associates during their period of internship at either an EPA facility or an EPA stakeholder facility. This program will start on or about April 1, 2001 and continue for a three year period.

DATES: Applications must be received no later than 5:00 p.m., Eastern Time, February 23, 2001.

ADDRESSES: Applicants must submit one signed original plus two (2) copies of the application including all information required by the application kit. Applications must be mailed to: Linda K. Smith, EPA Intern Program, US EPA (2201A), Washington, DC 20460. If delivered by courier service, the address is: Linda K. Smith, Associate Director for Resources Management, Office of Environmental Justice, US EPA, Room 2224 Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20004, Telephone: 202–564–2602.

FOR FURTHER INFORMATION CONTACT: Linda K. Smith, US EPA, Phone: 202–564–2602, E-mail: *smith.linda@epa.gov,* or by Fax: 202–501–1162.

SUPPLEMENTARY INFORMATION:

Background

The environmental protection student internship program is designed to provide undergraduate and graduate students from accredited universities and colleges with opportunities for environmental training experiences at EPA and other venues in which the student intern can receive a meaningful learning experience. The Program will be managed by the Office of Environmental Justice. EPA managers at Headquarters, Regional Offices, and Laboratories will develop and sponsor new training or research projects that will further the student interns' understanding of environmental and health protection issues and abatement techniques. The projects are sufficiently narrow in scope to allow the student to complete the project in a 3–6 month period by working full-time during the summer and/or part-time during the school year. Students selected to receive an internship are awarded a stipend based on their level of education and length of the project period.

EPA is expanding its institutional commitment to Environmental Stewardship and Health Protection. The Agency has identified several areas in which student interns would benefit by practical, on the job training experiences. These areas include but are not limited to:

- Environmental Policy, Regulation, & Law—Training in this area includes participation in the review and evaluation of existing policies and regulations, as well as the development of new policies. Training relating to compliance with policies and regulations is included.
- Environmental Management & Administration—This area focuses on providing training in how to implement and improve management goals; how to develop cooperative environmental management strategies.
- Environmental Science—This area focuses in training on field studies and laboratory research.
- Public Relations and Communications—This broad category provides the Intern with the opportunity to receive training relating to how public opinion affects environmental issues. Internet surveys, tools for

presentations, creation of pamphlets for informing about environmental protection could be part of a training opportunity.

• Computer Programming and Development—The student intern would receive training relating to developing computer programs for reaching different stakeholders. A project of this type could easily be a training opportunity at a community or grassroots organization facility.

A primary objective of the EPA is to plan and support active stewardship of the environment, of the public health, and to sustain communities at a time of increased pressures on these resources and decreasing funds for programs. Part of the strategy is to transfer US EPA's technologies, techniques, and methods to the community-at-large, especially the next generation of environmental professionals is to both increase their capability and to increase their diversity. EPA's programs and activities offer unique training opportunities to develop skills that can be transferred to the non-Federal community. An effective mechanism to affect this transfer is through the establishment of a student internship program. This cooperative agreement between US EPA and the recipient will promote these objectives The statutes under which the US EPA will conduct this intern program include:

a. *Clean Water Act,* Section 104(b)(3): conduct and promote the coordination of research, investigations, experiments, training, demonstration, surveys, and studies relating to the causes, extent, prevention, reduction, and elimination of water pollution.

b. *Safe Drinking Water Act,* Sections 1442(b)(3): develop, expand, or carry out a program (that may combine training, education, and employment) for occupations relating to the public health aspects of providing safe drinking water.

c. *Solid Waste Disposal Act,* Section 8001(a): conduct and promote the coordination of research, investigations, experiments, training, demonstrations, surveys, public education programs, and studies relating to solid waste management and hazardous waste management.

d. *Clean Air Act,* Section 103(b)(3): conduct and promote the coordination and acceleration of research, investigations, experiments, demonstrations, surveys, and studies related to the causes, effects (including health and welfare effects), extent, prevention, and control of air pollution.

e. *Toxic Substances Control Act,* Section 10(a): conduct research, development, and monitoring activities on toxic substances.

f. *Federal Insecticide, Fungicide, and Rodenticide Act,* Section 20(a): conduct research on pesticides.

g. *Marine Protection, Research, and Sanctuaries Act,* Section 203: conduct research, investigations, experiments, training, demonstrations, surveys, and studies relating to the minimizing or ending of ocean dumping of hazardous materials and the development of alternatives to ocean dumping.

Catalog of Federal Domestic Assistance (CFDA)

This EPA Intern Program is listed in the Catalog of Federal Domestic Assistance under 66.607 Training and Fellowships for the Environmental Protection Agency.

Program Description

The objective of the program is to provide training opportunities to students interested in pursuing environmental careers. The proposed cooperative program will be administered by the Recipient in response to intern opportunities available at US EPA or other Federal or non-Federal organizations which offer opportunities for training in environmental protection.

In cooperation with EPA, the recipient will select and employ student interns to work on individual projects in response to internship opportunities established by the program offices within US EPA. Student interns are not EPA employees and the recipient, and cooperation with EPA, will develop an orientation program that will explain the intern's roles, responsibilities, and limitations. The student interns must be undergraduate students, graduate students, or college graduates who have been accepted into graduate programs and will begin their studies within 9 months of accepting an internship position. Student interns may be studying areas such as environmental science, earth science, environmental engineering, geodesy, chemistry, physics, oceanography, biology, fishery science, geography, resource economics, risk assessment, policy analysis, computer science, and law. The EPA Code of Federal Regulations, 40 CFR part 45.135(a), states that ''Trainees must be citizens of the United States, its territories, or possessions, or lawfully admitted to the United States for permanent residence.''

All internship projects will be carried out under a written training plan with the technical guidance of a mentor or Technical advisor from EPA or another sponsoring organization. These projects must be designed to provide learning experiences for the Interns that will make them competitive for employment opportunities in both the public and private sector. Final details for individual training plans shall be developed by the recipient in consultation with the Project Officer or the individual Technical Advisor in accordance with the ''Statement of Substantial Involvement between US EPA and the Recipient'' described below.

The maximum period that a student intern may participate in the program on a full or part time basis with funding from EPA is six months. The Agency may fund one additional three month extension of an internship to enable the student to complete a project.

The recipient may establish environmental protection internship opportunities with organizations other than EPA. EPA may choose to fund and sponsor these internships or the recipient can obtain sponsorship or funding from non-EPA sources. Please note that under OMB Circular A–122 applicable to assistance agreements with non profit organizations, general fund-raising costs are not allowable.

There is not a fixed number of Internships per year under this program. The actual number will depend on opportunities and funding identified by offices within US EPA. Internships may be located at US EPA or at facilities of other organizations with missions relating to environmental protection. If interns are required to relocate to such locations for the duration of the internship, EPA will provide financial assistance to the recipient in an amount up to $500 to offset the interns relocation expenses. Interns will be provided individual project assignments for each internship.

Under this Cooperative Agreement, the Recipient shall make an effort to advertise and promote the availability of these internships to Native Americans, Hispanic, African, Asian and other minorities (including women) at all levels so as to provide opportunities for a diverse group of students to participate in this program.

Definitions

1. *Student Intern*—Individual trainee who will be provided with and perform internships under this cooperative agreement.

2. *Project Officer*—The US EPA Project Officer is that individual specifically named by US EPA to manage this program.

3. *Technical Advisor*—The US EPA employee responsible for providing technical guidance on the specific

project(s) assigned to the Intern and for the Intern's individual development and progress. Because the student interns will be employees of the recipient organization rather than the Agency, EPA technical advisors do not provide day to day supervision of student interns.

4. *Intern Opportunity/Project*—An opportunity for an internship which is documented and has funds obligated for its costs. In general, these opportunities will be assignments within existing US EPA programs and ongoing projects and will be performed at the site of the project an EPA facility. In some cases, the assignment may involve an intern training at locations other than an EPA facility such as a community organization facility; a non-profit organization facility; or a local government, state government, or tribal government facility.

Maximum EPA Financial Participation in Stipends (per Week) and General Background Requirements of Internships

1. $400 ($10.00/hr) 1–4 full years of academic study.
2. $500 ($12.50/hr) Undergraduate degree and acceptance in graduate school.
3. $600 ($15.00/hr) Undergraduate Degree and superior academic standard (top 1/3, 2.9/4 GPA overall, & 3.5/4 GPA in Major) and accepted into graduate school.
4. $700 ($17.50/hr) Completed 60 hrs Graduate level or completed Masters or law degree and accepted into PhD or L.L.M. program.

Unless included in the Intern opportunity description, overtime is not anticipated. In the event that overtime is required, the duration of the internship shall be reduced or additional funds shall be obligated or Compensatory time shall be given in lieu of overtime to pay for it.

5. In the event that an Intern voluntarily terminates or is terminated by the recipient for cause (*e.g.* failing to carry out his or her training plan or engaging in disruptive behavior), the Recipient shall make every effort to select another intern and, if not practicable, advise EPA to de-obligate the remaining funds committed to the internship.

Funding Availability

US EPA funding for this Program will be a minimum of $500,000 from FY01 funds during the first year. Each internship or group of internships, beyond the first, shall be funded as a separate amendment to the master agreement. There is no set timetable for announcement of Internships and they may occur throughout the year.

Matching Requirements

Cost sharing is not required for the internship program.

Type of Funding Instrument

The US EPA Intern Program shall be awarded as a Cooperative Agreement since EPA anticipates that there will be substantial involvement between the EPA, the Recipient, and the Interns (after their selection).

Statement of Substantial Involvement between US EPA and the Recipient

In carrying out the work program set forth in the project description, US EPA and the Recipient agree to meet the programmatic objective of this agreement as stated.* US EPA involvement will consist of the following activities:

1. US EPA will provide descriptions of available student intern opportunities including academic background and prior work experience that would make the internship experience meaningful to the student.
2. EPA personnel will discuss internship opportunities with prospective interns and provide advice to the recipient relating to the ''fit'' between a prospective intern's academic background and work experience and the training available under the internship opportunity. However, EPA personnel will not select or make offers to prospective intern.
3. After considering EPA's advice, and making its own assessment of the fit between prospective interns' qualifications and interests and the internship opportunity, the Recipient is responsible for selecting the intern, making the offer of the internship, and arranging an orientation program and start date.
4. The recipient and EPA will collaboratively develop the student interns training plan. EPA will provide a technical advisor to interact with each student intern as the intern carries out his or her training plan. The technical monitor shall provide technical guidance and support to the Intern in developing the skills necessary to perform the work in the chosen environmental arena. However, EPA's technical advisor will not supervise the intern on a day to day basis. The Recipient must manage time and attendance and monitor the interns' progress towards completing his or her training plan.
5. EPA shall provide liaison to interact with the Recipient and Senior Management on the progress of meeting the programmatic objectives of this Cooperative Agreement.

*Summary Section: The programmatic objective of this intern program is to provide unique training opportunities for cooperative study, research, and development that would be of major benefit in advancing the number and diversity of environmental professionals.

Eligibility Criteria

Any non profit organization as described in OMB Circular A–122 may submit a proposal. Please note that there are restrictions on the extent to which EPA can award financial assistance to organizations described by Section 501(c)(4) of the Internal Revenue Code who engage in lobbying.

Award Period

The initial Master Agreement shall be for a period of three (3) years. US EPA shall consider continued funding for the project upon: (a) Satisfactory progress toward the stated agreement goals, and the determination by US EPA that the continuation of the program would be in the best interest of the Government; and (b) availability of funds. The awards must have scopes of work that can easily be separated into annual increments of meaningful work which represent solid accomplishments if prospective funding is not made available to the applicant. This submission in no way obligates US EPA to extend this agreement, nor is this paragraph to be interpreted as a promise that future funds will be available. Stipend levels, and benefits may be adjusted for Cost of Living Allowances for each continuation year.

Administrative Costs

Funds to support the environmental professional intern program shall be given directly to the Recipient. Administrative costs shall be negotiated as part of the Master Agreement award and shall be based on and paid on a per Internship basis. These costs may be fixed, time dependent, Intern stipend dependent, or a combination as proposed by the Recipient.

Indirect Costs

The total dollar amount of the indirect costs proposed in an application under this program must not exceed the indirect cost rate negotiated and approved by a cognizant Federal agency prior to the proposed effective date of the award.

Application Requirements

Each Prospective Recipient shall submit a package containing completed:

1. SF–424 (including SF–424A & SF–424B). (Available on the Internet at *http://www.whitehouse.gov/OMB/grants/#forms*).

2. A budget with necessary supporting details. This budget should be based on a hypothetical intern opportunity at a stipend level of $500 per week, with an allowance for required field trip travel of $2,000, and a relocation allowance of $500. Because it is anticipated that this agreement will be extended to include additional internships beyond the first, supporting information should be included to determine the full cost to the government of additional internships which may have any of the suggested stipend levels, have durations ranging 6 to 9 months, and be with or without relocation or travel allowances. This information should also contain details on what services and benefits are included (*i.e.* sick leave, tax withholding, insurance, etc.) and their estimated cost to interns; as well as, what, if any, allowances are made for vacation leave and/or sick leave. Holidays observed by the office hosting the intern will be considered paid holidays.

3. Curriculum Vitae for each individual and critical senior staff assigned to the program,

4. Copy of a current approved Negotiated Indirect Cost Rate Agreement,

5. SF-LLL ''Disclosure of Lobbying Activities''

6. ''Certifications Regarding Lobbying Activities''

7. EPA Form 5700–49 ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters''

8. A narrative description of the applicant's proposed plan for carrying out its environmental professional internship program. This narrative shall include:

(a) A description of the Intern Program, how they would implement it and conduct its operation. Alternatives and variations with regard to the timing of items 4 and 5 within the ''Description of the Intended Operation of the Intern Program for each Internship'' detailed above may be proposed.

(b) Proposed method of advertising for and pre-screening candidate Interns and supervising interns as they carry out their training plans.

(c) Proposed benefits offered to Interns (*e.g.* tax withholding, health insurance, liability insurance, workman's compensation, etc.) as employees of the applicant.

(d) Past history of the prospective Recipient in carrying out similar programs, and how carrying out the environmental professional internship program will further the applicant's mission.

(e) Ability to use the Internet for all aspects of the intern program.

9. Proof of Status For First Time Eligible Non-Profit Applicants.

10. EPA Form 5700–48 ''Procurement System Certification''

11. EPA Form 4700–4 ''Pre-award Compliance Review report for All Applicants * * *.''

Application Forms and Kit

The Grant Application Kit can be obtained by calling 202–564–5310. It is also available in PDF format at *http://www.epa.gov/ogd/appkit.htm.*

You can also visit your local public library and copy the forms from the **Federal Register** in which this document is published; many federal offices use the forms and have copies available. A tutorial for grant applicants is available at: *http://www.epa.gov/seahome/grants/src/grant.htm* where the forms can be printed.

Project Funding Priorities

Responsiveness of the application to the programmatic objectives of the Intern program as noted in the Summary section and restated in the Type of Funding Instrument section above.

Evaluation Criteria

The proposals from applicants will be evaluated and ranked on a ''high, medium or low'' basis. High rankings are the most desirable. These rankings will be considered by EPA management in deciding which proposal, on balance, will provide the best value to both the Government and prospective interns. The evaluation factors that will be considered include:

1. Costs for operating the proposed Intern Program.

2. The applicant's proposed approach to carrying out the program and proposed time lines for filling internships.

3. Services and benefits available to the Interns relative to their cost to EPA, the applicant and the student interns

4. Proposed method for advertising for and pre-screening candidate Interns.

5. Past history of the prospective Recipient in operating similar programs.

6. Qualifications of proposed senior staff.

Selection Procedures

Each application will receive an independent, objective review by a panel qualified to evaluate the applications submitted. The Independent Review Panel, consisting of at least three individuals in addition to the Selecting Official US EPA Federal Program Officer, will review, evaluate, and rank all applications based on the criteria stated above. The final decision on award will be based upon the panel's overall ranking of the application and a determination by the Selecting Official that the Recipient's application meets the Project Funding Priorities.

Other Requirements

Travel Expenses of selected Interns

EPA may provide additional financial support for travel and transportation for student interns assigned to EPA projects requiring field work as documented in the description of the Intern Opportunity and the Intern's training plan. The funds will be included as part of the original funding to the Recipient at the time the internship project is initiated or at a later date by way of an amendment. Student interns shall complete Recipient's travel approval form prior to each trip, complete a travel reimbursement form at the conclusion of each trip, and a travel experience report at the conclusion of each trip for the Recipient. The US EPA Technical Advisor shall sign the form to acknowledge the trip is consistent with the intern's training plan prior to any action by the Recipient. Travel advances for Interns shall be available from the Recipient as needed. All travel and transportation required for field work shall be paid by the Recipient out of funds included in the agreement.

Restrictions

This is a short term training program for students. Interns will not be used to replace US EPA employees formerly employed under the Office of Personnel Management student appointing authorities, to replace temporary or term appointments, or to replace or fill-in for full or part-time US EPA positions vacated by the Voluntary Separation Program or Reduction in Force. Participants will not be selected or used to perform personal services. The Recipient and the Agency shall avoid any actions that create the appearance that the intern is a Federal employee or is being used by EPA to obtain personal services. The relationship between the Recipient and Interns is that of Employer and Employee. The Recipient must provide a health benefits option, must deduct applicable state and federal taxes, and is responsible for payment, discipline, leave approval, termination, etc. for each Intern. Nothing in this agreement or its supplements shall be deemed to create an employer-employee relationship between the US EPA and

an Intern. Former US EPA employees are not eligible for this program within two years of employment at US EPA. Former EPA employees must qualify as students to participate in the program.

(1) *Federal Policies and Procedures.* Recipients are subject to all Federal laws and Federal and USEPA policies, regulations, and procedures applicable to Federal financial assistance awards.

(2) *Past Performance.* Unsatisfactory performance under prior Federal awards will be considered in evaluating an applicant's proposal.

(3) *Preaward Activities.* If applicants incur any costs prior to an award being made, they do so solely at their own risk of not being reimbursed by the Government. Notwithstanding any verbal or written assurance that may have been received, there is no obligation on the part of the USEPA to cover pre-award costs except to the extent authorized at 40 CFR 30.25(f).

(4) *No Obligation for Future Funding.* If an application is selected for funding, the USEPA has no obligation to provide any additional future funding in connection with the award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of the USEPA.

(5) *Delinquent Federal Debts.* No award of Federal funds shall be made to an applicant who has an outstanding delinquent Federal debt until either:

i. The delinquent account is paid in full,
ii. A negotiated repayment schedule is established and at least one payment is received, or
iii. Other arrangements satisfactory to USEPA are made.

(6) *Name Check Review.* All non-profit applicants are subject to a name check review process. Name checks are intended to reveal if any key individuals Interned with the applicant have been convicted of or are presently facing criminal charges such as fraud, theft, perjury, or other matters which significantly reflect on the applicant's management honesty or financial integrity. Key individuals cannot be currently suspended, debarred, or otherwise ineligible from participating in Federal financial assistance.

(7) *Primary Applicant Certifications.* All primary applicants must submit a completed form CD–511, ''Certifications Regarding Debarment, Suspension and Other Responsibility Matters; Drug-free Workplace Requirements and Lobbying,'' and the following explanations are hereby provided:

i. *Nonprocurement Debarment and Suspension.* Prospective participants (as defined at 15 CFR part 26, section 105) are subject to 15 CFR part 26, ''Nonprocurement Debarment and Suspension'' and the related section of the certification form prescribed above applies;
ii. *Drug-Free Workplace.* Recipients (as defined at 15 CFR part 26, section 605) are subject to 15 CFR part 26, subpart F, ''Government requirements for Drug-Free Workplace (Grants)'' and related section of the certification form prescribed above applies;
iii. *Anti-Lobbying.* Persons (as defined at 15 CFR part 26, section 105) are subject to the lobbying provisions of 31 U.S.C. 1352, ''Limitations on use of appropriated funds to influence certain Federal contracting and financial transactions,'' and the lobbying section of the certification form prescribed above applies to applications/bids for grants, cooperative agreements, and contracts for more than $100,000 * * *.''
iv. *Anti-Lobbying Disclosures.* Any applicant that has paid or will pay for lobbying using any funds must submit an SF–LLL, ''Disclosure of Lobbying Activities,'' as required under 15 CFR part 28, Appendix B.

(8) *False Statements.* A False statement on an application is grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001.

(9) *Intergovernmental Review.* Applications under this program are not subject to executive Order 12372, ''Intergovernmental Review of Federal Programs.''

Approved for Publication:

Dated: December 22, 2000.

Barry E. Hill,

Director, Office of Environmental Justice, U.S. Environmental Protection Agency.

[FR Doc. 01–419 Filed 1–5–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6930–4]

Science Advisory Board; Notification of Public Advisory Committee Meeting

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Dioxin Reassessment Review Committee (DRRC) of the US EPA Science Advisory Board (SAB), may, depending on progress achieved in developing its report (see below), meet in a public teleconference on Tuesday, January 23, 2000 between 2 and 4:30 p.m. The meeting will be coordinated through a conference call connection in Room 6013 in the USEPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. The public is encouraged to attend the meeting in the conference room noted above. However, a limited number of the public may also attend through a telephonic link, thirty-two lines have been reserved for this purpose. Additional instructions about how to participate in the meeting can be obtained by calling Ms. Wanda Fields prior to the meeting at (see contact information below).

Purpose of the Meeting—The Committee is planning a teleconference for the above noted date on a contingency basis. The teleconference will be convened only if, in the opinion of the DRRC Chair, it is needed to address issues that require further discussion prior to completion of the Committee's report. A decision as whether or not the teleconference (announced in this meeting notice) will be convened will be made by close of business, Friday, January 12, 2000, 11 days prior to the tentatively scheduled date. The decision on the teleconference will be posted to the SAB website *(www.epa.gov/sab);* or members of the public may call or email Ms. Wanda Fields at the telephone and email address provided below.

Availability of Review Materials—If the teleconference is to be held, a list of the issues to be discussed, along with a draft meeting agenda, will be posted on the SAB website *(www.epa.gov/sab)* under the *Agenda* heading on January 12, 2000. If the meeting is canceled, a notice will be posted on the SAB website to that effect as well.

FOR FURTHER INFORMATION: Any member of the public wishing further information concerning this meeting should contact Mr. Samuel Rondberg, Designated Federal Officer, EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone (301) 812–2560, FAX (410) 286–2689; or via e-mail at: samuelr717@aol.com. Because of the limited time for discussion during the teleconference, oral comments from the public will not be taken (extensive oral comments were taken earlier at the November 1–2, 2000 meeting—see 65 FR 60190, dated October 10, 2000). Written comments may be submitted for consideration by the Committee, and should be sent to Ms. Wanda Fields, EPA Science Advisory Board, Mail Code 1400A, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington DC 20460. (Telephone (202) 564–4539, FAX (202) 501–0582; or via e-mail at fields.wanda@epa.gov).

Comments should be supplied in the following formats: one hard copy with original signature (and 25 copies), and one electronic copy via e-mail to Mr. Rondberg or Ms. Fields (acceptable file formats: WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 95/98 format). Written comments must arrive at the SAB no later than January 16, 2000. Please note that the Committee had earlier extended the period for accepting written comments. The date given above is the deadline for receipt of ALL written comments.

Meeting Access—Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact Mr. Rondberg at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: December 21, 2000.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 01–464 Filed 1–5–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6930–5]

Science Advisory Board; Notification of Public Advisory Committee Meeting

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Clean Air Scientific Advisory Committee (CASAC) Technical Subcommittee for Fine Particle Monitoring will meet on Monday, January 22, 2001 at the US EPA Environmental Research Center (ERC), Classroom 2, Route 54 and Alexander Drive, Research Triangle Park, NC. The meeting will begin at 8:30 am and end no later than 5 pm, Eastern Time. The meeting is open to the public, however, due to limited space, seating will be on a first-come basis. For further information concerning the meeting, please contact the individuals listed below. Important Notice: Documents that are the subject of CASAC reviews are normally available from the originating EPA office and are not available from the CASAC Office—information concerning availability of documents from the relevant Program Office is included below.

Background—This technical subcommittee of CASAC was established in 1996 to provide advice and comment to EPA (through CASAC) on appropriate methods and network strategies for monitoring fine particles in the context of implementing the revised national ambient air quality standards (NAAQS) for particulate matter.

Purpose of the Meeting—At this meeting, the Subcommittee will gather information and receive briefings from Agency Staff and outside entities.

Currently, EPA is in the process of preparing a revised criteria document and related materials in anticipation of reviewing the National Ambient Air Quality Standard (NAAQS) for Particulate Matter (PM). As part of that review and in light of the ongoing effort to monitor particles, particularly fine particles, there is an increasing need to have effective and efficient methods to continuously monitor PM mass. Such monitoring presents significant problems and currently, the regulations in place make it difficult to qualify a continuous monitor as an equivalent method to the designated Federal Reference Method (FRM) approach.

The CASAC Technical Subcommittee for Fine Particle Monitoring is soliciting public input on the development of technologies and approaches that would provide continuous monitoring of airborne PM with a sufficient accuracy and precision that it could be used for regulatory purposes. We invite interested individuals, companies, and state and local regulatory agencies to submit ideas (in writing or at the meeting) as to a framework in which conflicting demands of convenience in monitoring, accuracy, precision, and concordance with the existing base of monitoring data could be developed. At this time, we are not looking for descriptions of specific devices, but rather possible approaches (within the regulatory environment) that would encourage development, testing, and qualification of new instruments for this purpose.

Presentations may be made to the Subcommittee either orally or via a poster. Posters will be set up either within the meeting room or in the hallway outside, depending on the number of posters requested. Appropriate time will be allocated during the mid-point of the meeting to evaluate posters and to discuss these posters with presenters.

Availability of Review Materials—A brief white paper, outlining some of the issues under consideration, will be available from EPA Staff on or about January 9th. For further details, or to obtain a copy of the draft white paper, please contact Tim Hanley, US EPA, Office of Air Quality Planning and Standards (MD–14), Research Triangle Park, NC 20771, phone (919) 541–4417 or via e-mail at: *hanley.tim@epa.gov.*

FOR FURTHER INFORMATION: Members of the public desiring additional information about the meeting should contact Mr. Robert Flaak, Designated Federal Officer, Clean Air Scientific Advisory Committee, Science Advisory Board (1400A), Suite 6450, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone/voice mail at (202) 564–4546; fax at (202) 501–0582; or via e-mail at *flaak.robert@epa.gov.* A copy of the draft agenda will be posted on the SAB Website (*www.epa.gov/sab*) (under the ''Agenda'' subheading) approximately 12 days before the meeting.

Members of the public who wish to make a brief oral presentation to the Subcommittee, or make arrangements for a poster, must contact Mr. Flaak in writing (by letter or by fax—see previously stated information) no later than 12 noon Eastern Time, Wednesday, January 17, 2001 in order to be included on the Agenda. Public comments will be limited to approximately ten minutes per speaker or organization, unless other arrangements have been made in advance with Mr. Flaak for additional time. The request should identify the name of the individual making the presentation, the organization (if any) they will represent, any requirements for audio visual equipment (*e.g.,* overhead projector, 35mm projector, chalkboard, etc.), and at least 35 copies of an outline of the issues to be addressed or of the presentation itself. Those requesting a poster should provide their requirements in the same request (Posters, or other display materials can be wall mounted, or placed on panels or tables).

Providing Oral or Written Comments at SAB Meetings

The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. In general, each individual or group making an oral presentation will be limited to a total time of ten minutes. For conference call meetings, opportunities for oral comment will be limited to no more than five minutes per speaker and no more than fifteen minutes total. Written comments (at least 35 copies) received in the SAB Staff Office sufficiently prior to a meeting date, may be mailed to the relevant SAB committee or subcommittee prior to its meeting; comments received too close to the meeting date will normally be provided to the committee at its meeting. Written comments may be provided to the relevant committee or subcommittee up until the time of the meeting.

Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (*http://www.epa.gov/sab*) and in The FY2000 Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564–4533 or via fax at (202) 501–0256.

Individuals requiring special accommodation at this meeting, including wheelchair access, should contact Mr. Flaak at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: December 28, 2000.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 01–465 Filed 1–5–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6924–8]

Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of water quality criterion for the protection of human health: methylmercury.

SUMMARY: Pursuant to the Clean Water Act (CWA) section 304(a), EPA is announcing the availability of its recommended water quality criterion for methylmercury. This water quality criterion describes the concentration of methylmercury in freshwater and estuarine fish and shellfish tissue that should not be exceeded to protect consumers of fish and shellfish among the general population. EPA expects the criterion recommendation to be used as guidance by States, authorized Tribes, and EPA in establishing or updating water quality standards for waters of the United States and in issuing fish and shellfish consumption advisories. This is the first time EPA has issued a water quality criterion expressed as a fish and shellfish tissue value rather than as a water column value. This approach is a direct consequence of the scientific consensus that consumption of contaminated fish and shellfish is the primary human route of exposure to methylmercury. EPA recognizes that this approach differs from traditional water column criteria, and will pose implementation challenges. In this notice, EPA is providing suggested approaches for relating the fish and shellfish tissue criterion to concentrations of methylmercury in the water column. EPA also plans to develop more detailed guidance to assist States and Tribes with implementation of the methylmercury criterion in water quality standards and related programs. EPA believes that flexibility will be needed when designing control programs to meet this water quality criterion because mercury is highly persistent in the environment and because air deposition is the primary source of mercury for many waterbodies.

ADDRESSES: Copies of the complete document, titled *Water Quality Criterion for the Protection of Human Health: Methylmercury* can be obtained from EPA's National Service Center for Environmental Publications (NSCEP), telephone number 1–800–490–9198. Alternatively, the document and related fact sheet can be obtained from EPA's web site at *http://www.epa.gov/waterscience/standards/methylmercury/* on the Internet. Copies of the draft EPA internal report *National Bioaccumulation Factors for Methylmercury,* the peer review report on the draft bioaccumulation factors, responses to public comments on the notice of intent to develop a methylmercury water quality criterion, and responses to peer review comments on the methylmercury reference dose are in Water Docket W–00–20 methylmercury. These materials are available for inspection at the Water Docket Room EB 57, 401 M Street SW, Washington, DC 20460, open between 9 am and 3:30 pm EST. Appointments to review the material may be made by calling 202–260–3027.

FOR FURTHER INFORMATION CONTACT: For general questions regarding the methylmercury water quality criterion guidance, contact Mary Manibusan, USEPA, Health and Ecological Criteria Division (4304), Office of Science and Technology, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or call (202) 260–3688; fax (202) 260–1036; or e-mail manibusan.mary@epa.gov. For specific issues regarding mercury bioaccumulation, contact Erik Winchester, USEPA, Health and Ecological Criteria Division (4304), Office of Science and Technology, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or call (202) 260–6107. For questions about implementation of the water quality criterion, contact William Morrow, USEPA, Standards and Health Protection Division, Office of Science and Technology, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or call (202) 260–3657.

SUPPLEMENTARY INFORMATION: This Supplementary Information Section is organized as follows:

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I. Introduction

Pursuant to section 304(a)(1) of the Clean Water Act (CWA), the Environmental Protection Agency is announcing the availability of EPA's recommended section 304(a) human health water quality criterion for methylmercury. Section 304(a) human health ambient water quality criteria are numeric guidance values considered to be protective of human health for pollutant concentrations in aquatic media, such as ambient waters and edible tissues of aquatic organisms. EPA's recommended section 304(a) water quality criteria provide guidance

for States and authorized Tribes to use in establishing water quality standards and, when adopted into water quality standards and approved for CWA purposes, may form a basis for controlling discharges or releases of pollutants. Section 304(a) water quality criteria also provide guidance to EPA when promulgating Federal regulations under CWA section 303(c) when such actions are necessary. Under the CWA and its implementing regulations, States and authorized Tribes are to adopt water quality criteria to protect designated uses. EPA's recommended human health water quality criteria do not substitute for the Act or regulations, nor are they regulations themselves. Thus, EPA's recommended section 304(a) water quality criteria do not impose legally binding requirements. States and authorized Tribes retain the discretion to adopt, where appropriate, other scientifically defensible water quality standards that differ from these recommendations. EPA may change the section 304(a) water quality criteria in the future.

Mercury is a complex multi-media pollutant that requires a more unique approach to source management, pollution reduction and control, and development of a water quality criterion than is typically required for a less complex pollutant. In the United States, humans are exposed primarily to methylmercury rather than to inorganic mercury. The dominant exposure pathway is through consumption of contaminated fish and shellfish rather than from ambient water. The water quality criterion published in this notice is for methylmercury, and it is expressed as a fish tissue (including shellfish) residue criterion rather than a water column criterion. Henceforth, EPA will refer to today's methylmercury water quality criterion as a fish tissue residue criterion, which should be understood to include shellfish as well. The Agency's basis for expressing the methylmercury water quality criterion in this format is discussed later in this notice and in more detail in the water quality criterion document titled *Water Quality Criterion for the Protection of Human Health: Methylmercury* (USEPA, 2001), which is available today.

EPA recognizes that a fish tissue residue water quality criterion is new to States and authorized Tribes and will pose implementation challenges for traditional water quality standards programs. Water quality standards, water quality-based effluent limits, total maximum daily loads, and other activities generally employ a water column value. In this notice, EPA suggests approaches for relating the fish tissue residue water quality criterion to concentrations of methylmercury in water. EPA also plans to develop guidance to assist States and Tribes to implement this methylmercury water quality criterion in their water quality programs. EPA believes that the range of implementation issues would be addressed best through broad national implementation guidance, and will work to develop such guidance with input from the public. Mercury is highly persistent in the environment and reductions in environmental concentrations are likely to occur over years or decades. For many waterbodies the primary source of mercury pollution is through air deposition and not pont source discharge, EPA believes that flexibility may be appropriate as water quality standards based on this methylmercury water quality criterion are implemented. Flexible approaches will enable environmental protection to be achieved efficiently given the resource constraints that exist for both regulators and the regulated community.

This notice also discusses the unique aspects of mercury and methylmercury as an environmental pollutant; announces EPA's intention to publish methylmercury water quality criterion implementation guidance, which will support prevention and reduction of mercury contamination of surface water and fish; and invites the public to provide information and their views on approaches to prevent or reduce mercury pollution and to implement water quality standards for methylmercury.

This document has been approved for publication by the Office of Water, United States Environmental Protection Agency. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

II. Background Information

A. What Are Human Health Ambient Water Quality Criteria?

Human health ambient water quality criteria (AWQC) are numeric values considered to be protective of human health for pollutant concentrations in aquatic media, such as ambient waters and edible tissues of organisms. Under section 304(a) of the Clean Water Act (CWA), water quality criteria are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects. Protective assumptions are made regarding potential human exposure intakes. Water quality criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the pollutant concentrations in ambient water. Section 304(a)(1) of the CWA requires EPA to develop and publish, and from time to time revise, criteria for water quality accurately reflecting the latest scientific knowledge. EPA's recommended section 304(a) water quality criteria may serve as guidance for States and authorized Tribes in establishing water quality standards. The resulting standards may ultimately may provide a basis for controlling discharges or releases of pollutants. Section 304(a) water quality criteria also provide guidance to EPA when promulgating Federal regulations under CWA Section 303(c) when such actions are necessary.

B. How Is the 2000 Human Health Methodology Used?

In November 2000, EPA published the revised *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (hereafter the 2000 Human Health Methodology (USEPA, 2000a). See 65 FR 66444 (November 3, 2000). Previous to this, recommended human health ambient water quality criteria were developed using the 1980 *Ambient Water Quality Criteria National Guidelines* (hereafter the 1980 Methodology; USEPA 1980). The 2000 Human Health Methodology incorporates significant scientific advances that have occurred over the last two decades, particularly in the areas of cancer and noncancer risk assessments (using new information, procedures, and published Agency Guidelines), exposure assessments (using new studies on human intake and exposure patterns, and new Agency Guidelines) and methodologies to estimate bioaccumulation in fish.

EPA intends to use the 2000 Human Health Methodology to develop new section 304(a) water quality criteria for additional pollutants and to revise existing section 304(a) water quality criteria. The 2000 Human Health Methodology is an important component of EPA's efforts to improve the quality of the Nation's waters and enhance the overall scientific basis of water quality criteria. Furthermore, the 2000 Human Health Methodology should help States and authorized Tribes address their unique water quality issues and make risk management decisions to protect human health consistent with section 303(c). It will also afford them greater flexibility in developing their water quality programs. The 2000 Human Health provides the detailed means for developing water quality criteria,

including systematic procedures for evaluating cancer risk, noncancer health effects, human exposure, and bioaccumulation potential in fish.

One particular area of new science is in developing the Reference Dose (RfD) value. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of daily exposure to the human population (including sensitive subgroups) that is likely to be protective without an appreciable risk of deleterious health effects during a lifetime. For noncarcinogenic pollutants, the process for deriving a level of exposure considered to be without appreciable risk of effect has evolved over time. EPA has developed guidance on assessing noncarcinogenic effects of chemicals and for the RfD derivation. The 2000 Human Health Methodology recommends consideration of other issues related to the RfD process including integrating reproductive and developmental, immunotoxicity, and neurotoxicity data into the calculation. In the 2000 Human Health Methodology, EPA recommends using quantitative dose-response modeling for the derivation of RfDs when the available data support its use. EPA has provided additional guidance (in its Risk Assessment Technical Support Document (USEPA, 2000b)) to States and authorized Tribes on conducting their own risk assessments.

For exposure assessment, States and authorized Tribes are encouraged to use local studies on human fish and shellfish consumption that better reflect local intake patterns and choices. In the absence of local data, EPA recommends separate default fish consumption values for the general population, recreational fishers and subsistence fishers. A factor to account for other sources of exposure, such as other fish, non-fish food, and air, is included when deriving AWQC for noncarcinogens and for carcinogens based on a nonlinear low-dose extrapolation. In other words, consumption of contaminated water and fish (including shellfish) are not the only exposures considered.

The 2000 Human Health Methodology places greater emphasis on the use of bioaccumulation factors (BAFs) for estimating potential human exposure to contaminants via the consumption of contaminated fish and shellfish than did the 1980 Methodology. BAFs reflect the accumulation of chemicals by aquatic organisms from all surrounding media (includes water, food, and sediment). Compared with bioconcentration factors, which reflect chemical accumulation by aquatic organisms from water only, BAFs are considered to be better predictors of chemical accumulation by fish and shellfish for chemicals where exposure from food and sediment is important (*e.g.,* highly persistent, hydrophobic chemicals). EPA prefers to use high quality field data (*e.g.,* water and fish data collected in the waterbody of interest) to derive BAFs over laboratory or model-derived estimates of BAFs. This preference is because field data best reflect site-specific factors that can affect the extent of bioaccumulation (*e.g.,* chemical metabolism, food web structure).

C. How Does EPA Use Its Recommended Section 304(a) Water Quality Criteria?

Water quality standards consist of designated uses, water quality criteria to protect those uses, a policy for antidegradation, and general policies for application and implementation. As part of the water quality standards triennial review process defined in section 303(c)(1) of the CWA, States and authorized Tribes are responsible for maintaining and revising water quality standards. Section 303(c)(1) requires States and authorized Tribes to review, and modify if appropriate, their water quality standards at least once every three years.

EPA's recommended section 304(a) water quality criteria form the basis for Agency decisions, both regulatory and nonregulatory, until superseded by EPA publication of new or revised section 304(a) water quality criteria. These recommended water quality criteria are used in the following ways: (1) As guidance to States and authorized Tribes in adopting water quality standards; (2) as guidance to EPA in promulgating Federal water quality standards; (3) to interpret a State's narrative water quality standard (in the absence of a State adopted numeric standard) in order to establish National Pollutant Discharge Elimination System (NPDES) water quality-based permit limits; and (4) for all other purposes of section 304(a) under the Act. It is important to emphasize the two distinct purposes that are served by the section 304(a) water quality criteria. The first is as guidance to the States and authorized Tribes in the development and adoption of water quality criteria that will protect designated uses (*e.g.,* aquatic life, primary contact recreation). The second is as the basis for promulgation of Federal water quality criteria for States or authorized Tribes when such action is necessary.

D. What Water Quality Criteria Must a State or Authorized Tribe Adopt Into Its Water Quality Standards?

States and authorized Tribes must adopt water quality criteria that protect designated uses. See CWA section 303(c)(2)(A). Water quality criteria must be based on a sound scientific rationale and must contain sufficient parameters or components to protect the designated uses, See 40 CFR 131.11(a). Water quality criteria may be expressed in either narrative or numeric format. States and authorized Tribes may employ one of four approaches when adopting water quality criteria: (1) Establish numerical values based on section 304(a) recommended water quality criteria; (2) modify the section 304(a) recommended water quality criteria to reflect site-specific conditions; (3) use other scientifically defensible methods to derive protective water quality criteria; and (4) establish narrative water quality criteria where numeric criteria cannot be determined or to supplement numeric water quality criteria. See 40 CFR 131.11(b).

EPA encourages States and authorized Tribes to use EPA's CWA section 304(a) water quality criteria as guidance in adopting water quality standards consistent with section 303(c) of the CWA and the implementing Federal regulations at 40 CFR Part 131. These water quality criteria are contained in EPA's last compilation of National Recommended Water Quality Criteria. See 63 FR 68354, December 10, 1998; correction in 64 FR 19781, April 22, 1999. In the future, EPA will be publishing new and revised section 304(a) water quality criteria guidance for pollutants of high priority and national importance based upon the 2000 Human Health Methodology. Because this process will take time, EPA encourages States and authorized Tribes, prior to publication of a revised section 304(a) water quality criterion, to make appropriate changes when necessary to their water quality standards to reflect the guidance in the 2000 Human Health Methodology. EPA expects that it would promptly consider for approval any new or revised water quality criterion submitted by a State or authorized Tribe that is based on the 2000 Human Health Methodology.

Once EPA publishes new or revised section 304(a) water quality criteria guidance that reflects the 2000 Human Health Methodology, EPA expects States and authorized Tribes to reassess their water quality standards and, where necessary, establish new or revised water quality criteria consistent with one of the four approaches described above. With today's publication of this section 304(a) human health water quality criterion for methylmercury, EPA is withdrawing the previous ambient human health water quality criteria for mercury (see 63 FR 68354,

December 10, 1998; correction in 64 FR 19781, April 22, 1999) as the recommended section 304(a) water quality criteria for States and authorized Tribes to use as guidance in adopting water quality standards. Implementation issues for this criterion are discussed in Section VIII of today's Notice.

E. May States and Authorized Tribes Adopt Water Quality Criteria Based on Local Conditions?

EPA encourages States and authorized Tribes to develop and adopt water quality criteria to reflect local and regional conditions. In the 2000 Human Health Methodology, EPA published default values for risk level, fish intake, drinking water intake, and body weight for use by EPA or States in deriving human health water quality criteria. EPA also intends to publish default bioaccumulation factors and relative source contribution (RSC) factors as chemical-specific water quality criteria are developed or revised. EPA believes these default values result in water quality criteria protective of the general population. States and authorized Tribes may also use these default values when deriving their own water quality criteria, or they may use other values more representative of local conditions if data have been collected supporting the alternative values. However, when establishing a numeric value based on a section 304(a) water quality criterion modified to reflect site-specific conditions, or water quality criteria based on other scientifically defensible methods, EPA strongly cautions States and authorized Tribes not to selectively apply data in order to ensure water quality criteria less stringent than EPA's section 304(a) water quality criteria. Such an approach would inaccurately characterize risk.

F. How Does 40 CFR 131.21 Affect Water Quality Criteria Adopted by States and Authorized Tribes?

On April 27, 2000, EPA published new regulations addressing its review and approval of water quality standards adopted by States and authorized Tribes. See 65 FR 24642 April 27, 2000. Under the new regulations, which are codified at 40 CFR 131.21(c)–(f), State or authorized Tribal water quality standards that were adopted, in effect, and submitted to EPA prior to May 30, 2000, are in effect for CWA purposes unless superseded by replacement Federal water quality standards. See 40 CFR 131.21(c). However, under the new regulation, State or authorized Tribal water quality criteria adopted and in effect after May 30, 2000, are in effect for CWA purposes only after EPA approval of any new or revised water quality standards. Therefore, any new or revised water quality criterion for methylmercury adopted by States or authorized Tribes would not take effect for CWA purposes until after EPA approves such standards.

III. Mercury Sources, Environmental Fate, and Implications for Water Quality Criterion Derivation

The 1997 *Mercury Study Report to Congress* (The Mercury Study) (USEPA, 1997a) describes mercury emission sources, fate and transport, exposure to humans and wildlife, human health and ecological impacts of mercury exposure, and control technologies for air emissions. The most recent data and reviews on human health impacts are described and updated in the *Water Quality Criterion for the Protection of Human Health: Methylmercury* (USEPA, 2001), that we are announcing the availability of today.

A. What Are the Mercury Emissions and Deposition Sources in the United States?

Based on the EPA's National Toxics Inventory, the highest emitters of mercury to the air include coal-burning electric utilities, municipal waste combustors, medical waste incinerators, chlor-alkali plants, hazardous waste combustors, and cement manufacturers. The Mercury Study estimated that the annual anthropogenic United States emissions of mercury in 1994–1995 was 158 tons. Roughly 87 percent of these emissions were from combustion sources, including waste and fossil fuel combustion. Contemporary anthropogenic emissions are only one part of the mercury cycle. Releases from human activities today are adding to the mercury reservoirs that already exist in land, water, and air, both naturally and as a result of previous human activities. The deposition of mercury from the atmosphere to land or water at any location comes from: (1) The natural global cycle (including re-emissions from the oceans); (2) regional sources; and (3) local sources. Local sources can include direct water discharges in addition to mercury from air emissions. Past uses of mercury, such as fungicide application to crops, are also a component of the present mercury burden in the environment. The Mercury Study estimated that, for 1995, the United States sources contributed approximately 3 percent (or 165 tons) of the total global mercury emissions (5,500 tons). The Mercury Study further estimated that, of United States anthropogenic mercury emissions, approximately one-third (52 tons) are deposited through wet and dry deposition within the lower 48 States. The remaining two-thirds (approximately 107 tons) of anthropogenically emitted mercury is transported outside of the United States' borders where it enters the global reservoir. In addition to mercury deposited from United States sources, approximately another 35 tons of mercury from the global reservoir is deposited for a total deposition of roughly 87 tons within the lower 48 States. In the United States, the highest deposition rates from anthropogenic and global contributions for mercury are predicted to occur in the southern Great Lakes and Ohio River valley, the Northeast and scattered areas in the South, with the Miami and Tampa areas having the most elevated levels in the South. The location of sources, the chemical species of mercury emitted, and the climate and meterology are key factors in where and how rapidly mercury deposition occurs.

B. How Does Mercury Cycle in the Environment?

Mercury cycles in the environment as a result of natural and human (anthropogenic) activities. The amount of mercury mobilized and released into the biosphere has increased since the beginning of the industrial age. Most of the mercury in the atmosphere is elemental mercury vapor, which can circulate in the atmosphere for up to a year (USEPA, 1997a). Mercury in the atmosphere can be widely dispersed and transported thousands of miles from likely sources of emission (USEPA, 1997a). Inorganic mercury in the atmosphere, when either bound to airborne particles or in a gaseous form, is deposited to soils and waterbodies through wet and dry deposition events. Wet deposition as precipitation is the primary mechanism for transporting mercury from the atmosphere to surface waters and land. After it deposits, mercury can be emitted back to the atmosphere, either as a gas or associated with particles, to be re-deposited elsewhere. As it cycles among the atmosphere, land, and water, mercury undergoes a series of complex chemical and physical transformations, many of which are not completely understood. Most of the mercury that ends up in water, soil, sediments, and plants and animals is in the form of inorganic mercury salts and organic forms of mercury, such as methylmercury. Detailed discussions of mercury chemistry can be found in Nriagu (1979) and Mason et al. (1994).

Mercury from air emissions can be deposited to watershed soils, where a

portion of it can be methylated through soil microbial activity. Mercury in soils can be washed from the watershed into wetlands, lakes, streams, and rivers where microbial activity in sediments converts inorganic mercury to methylmercury. In particular, wetlands appear to be key environments for microbially enhanced conversion of mercury into methylmercury. Once in aquatic systems, mercury can exist in dissolved or particulate forms and can undergo a number of chemical transformations. Contaminated sediments at the bottom of surface waters can serve as an important mercury reservoir, with sediment-bound mercury recycling back into the aquatic ecosystem for decades or longer. Mercury also has a long retention time in soils; as a result, mercury that has accumulated in soils may continue to be released to surface waters and other media for long periods of time, possibly hundreds of years.

C. Does Methylmercury Bioaccumulate?

Methylmercury is highly bioaccumulative and is the form of mercury that bioaccumulates most efficiently in the aquatic food web. Methylation of mercury is a key step in the entrance of mercury into food chains. The biotransformation of inorganic mercury species to methylated organic species in water bodies can occur in the sediment and the water column. Inorganic mercury can be absorbed by aquatic organisms but is generally taken up at a slower rate and with lower efficiency than is methylmercury. Methylmercury continues to accumulate in fish as they age. Predatory organisms at the top of aquatic and terrestrial food webs generally have higher methylmercury concentrations because methylmercury is typically not completely eliminated by organisms and is transferred up the food chain when predators feed on prey; for example, when a largemouth bass feeds on a bluegill sunfish, which fed on aquatic insects and smaller fish, all of which could contain some amount of methylmercury that gets transferred to the predator. Nearly 100 percent of the mercury that bioaccumulates in upper trophic level fish (predator) tissue is methylmercury (Bloom, 1992; Akagi, 1995; Kim, 1995; Becker and Bigham, 1995). Methylmercury BAFs for upper trophic level freshwater and estuarine fish and shellfish typically consumed by humans generally range between 500,000 and 10,000,000 (Glass *et al.* 1999; Lores *et al.,* 1998; Miles and Fink, 1998; Monson and Brezonik, 1998; Watras *et al.,* 1998; Mason and Sullivan, 1997).

Numerous factors can influence the bioaccumulation of mercury in aquatic biota. These include, but are not limited to, the acidity (pH) of the water, length of the aquatic food chain, temperature, and dissolved organic material. Physical and chemical characteristics of a watershed, such as soil type and erosion or proportion of area that is wetlands, affect the amount of mercury that is transported from soils to water bodies. Interrelationships among these factors are poorly understood and are likely to be site-specific. No single factor (including pH) has been correlated with extent of mercury bioaccumulation in all cases examined. Two lakes that are similar biologically, physically, and chemically can have different methylmercury concentrations in water, fish, and other aquatic organisms (Cope *et al.,* 1990; Grieb *et al.,* 1990; Jackson, 1991; Lange *et al.,* 1993). For more indepth discussions about the chemical, physical, and biological interactions affecting methylmercury bioaccumulation in aquatic organism see the compilation of papers in *Mercury Pollution: Integration and Synthesis* (Watras and Huckabee, 1994).

Because mercury methylation and entrance of methylmercury at the base of the food web is critical to the overall bioaccumulation process and magnitude of biomagnification, it is EPA's belief that reductions in the available pool of total mercury will ultimately lead to reduced concentrations in fish and shellfish typically consumed by humans. The extent to which concentrations of methylmercury will be reduced in fish and shellfish as a result of reduced pools of total mercury in the environment will be location specific and depend on the unique chemical, physical, and biological interactions that occur in a given system.

D. Why Is the 304(a) Human Health Water Quality Criterion for Methylmercury Expressed as a Fish Tissue Residue Value?

To derive section 304(a) water quality criteria for the protection of human health, EPA needs to conduct a human health risk assessment on the pollutant in question and gather information on the target population's exposure to the pollutant. Traditionally, EPA has expressed its section 304(a) water quality criteria guidance to protect human health in the form of pollutant concentrations in ambient surface water. To account for human exposure through the aquatic food pathway when deriving a water column-based water quality criterion, EPA uses national BAFs (USEPA, 2000a). A BAF is a ratio (in L/kg) that relates the concentration of a chemical in water to its expected concentration in commonly consumed aquatic organisms in a specified trophic level (USEPA, 2000a). A national BAF is meant to be broadly applicable to all waters in the United States, whereas a site-specific BAF is based on local data and integrates local spacial and temporal factors that can influence bioaccumulation. Some pollutants not only bioaccumulate, but also biomagnify in aquatic food webs. Biomagnification is a process whereby chemical concentrations increase in aquatic organisms of each successively higher trophic level due to increasing dietary exposures (*e.g.,* increasing concentrations from algae, to zooplankton, to forage fish, to predator fish). For pollutants that biomagnify, EPA's preferred approach for deriving national BAFs for use in deriving section 304(a) water quality criteria is to use empirical field data collected in the natural environment. With this preference in mind, EPA explored the feasibility of developing field-derived national methylmercury BAFs for each trophic level of the aquatic food chain consumed by humans (*i.e.,* trophic levels 2–4). Using Agency guidance on BAFs contained in the 2000 Human Health Methodology and procedures outlined in Volume III, Appendix D of the peer reviewed Mercury Study, EPA empirically derived draft national methylmercury BAFs for each trophic level of the aquatic food chain. The draft national BAFs were single value trophic level-specific BAFs calculated as the geometric mean of field data collected across the United States and reported in the open literature as well as other publically available reports. These draft methylmercury BAFs were compiled in a draft internal report and submitted to a panel of external scientific experts for peer review. The methylmercury water quality criterion document presents a summary of the draft internal BAF report as well as a summary of the peer review comments. The entire internal draft methylmercury BAF report and peer review report can be obtained from the Water Docket. See the **ADDRESSES** section of today's Notice to obtain a copy of the BAF peer report from the Water Docket.

Within any given trophic level, the individual empirically derived draft methylmercury BAFs generally ranged up to two orders of magnitude. This range in BAFs reflects the various biotic factors (such as food chain interactions and fish age/size) and abiotic factors (such as pH and dissolved organic carbon). The large range in the

individual empirically derived draft methylmercury BAFs results in uncertainty as to the ability of single trophic level-specific national methylmercury BAFs to accurately predict bioaccumulation of methylmercury in general across the waters of the United States. Presently, it is EPA's understanding that the mechanisms that underlie many of the influencing factors are not well understood and cannot be accurately predicted. As the science of methylmercury improves, in the future it may be possible to predict or model these processes and use such information to more accurately predict bioaccumulation. Until such time, EPA is unable to improve the predictive power of the methylmercury BAFs by universally accounting for influencing factors. This is not the case for other highly bioaccumulative pollutants, for example polychlorinated biphenyls (PCBs). For such pollutants, EPA has methods that improve the predictive capability of empirically derived or model predicted BAFs (*e.g.,* normalizing fish tissue concentrations to lipid and normalizing ambient water concentrations to dissolved and particulate organic carbon). EPA is actively involved in, and will continue to support, various types of research aimed at better understanding the fate of mercury in the environment and the processes that underlie methylmercury bioaccumulation. EPA hopes that results of new research will enable EPA to make better predictions about methylmercury bioaccumulation.

The BAF peer reviewers recognized the need for methylmercury BAFs and were supportive of most aspects of the methodology used to derive the draft national methylmercury BAFs. The peer reviewers did have issues with certain data used to derive the methylmercury BAFs and certain assumptions about food chain relationships. Overall, most of the peer reviewers believed that derivation of single-value trophic level-specific national BAFs for methylmercury that would be generally applicable to all waters of the United States under all conditions is difficult at best. This opinion was based on consideration of the highly site-specific nature of methylmercury bioaccumulation in aquatic environments and the large range in the empirically derived draft methylmercury BAFs. These peer reviewers recommended developing methylmercury BAFs on a more local or regional scale, if not on a site-specific basis. See the Addresses section of today's Notice to obtain a copy of the BAF peer report from the Water Docket.

After considering the various issues about mercury fate in the environment, the recent report by the National Academy of Sciences' National Research Council (NRC, 2000) on the toxicological effects of mercury (see Section V.A. of this Notice), and the methylmercury BAF peer review comments, EPA concluded that it is more appropriate at this time to derive a fish tissue (including shellfish) residue water quality criterion for methylmercury rather than a water column-based water quality criterion. EPA believes a fish tissue residue water quality criterion for methylmercury is appropriate for many reasons. A fish tissue residue water quality criterion integrates spacial and temporal complexity that occurs in aquatic systems and that affect methylmercury bioaccumulation. A fish tissue residue water quality criterion in this instance is more closely tied to the CWA goal of protecting the public health because it is based directly on the dominant human exposure route for methylmercury. The concentration of methylmercury is also generally easier to quantify in fish tissue than in water and is less variable in fish and shellfish tissue over the time periods in which water quality standards are typically implemented in water quality-based controls, such as NPDES permits. Thus, the data used in permitting activities can be based on a more consistent and measurable endpoint. Finally, this approach is consistent with how fish advisories are issued. Fish advisories for mercury are also based on the amount of methylmercury in fish tissue that is considered acceptable, although such advisories are usually issued for a certain fish or shellfish species in terms of a meal size. A fish tissue residue water quality criterion should enhance harmonization between these two approaches for protecting the public health.

Because EPA did not use national, empirically derived methylmercury BAFs to establish today's section 304(a) recommended methylmercury water quality criterion, EPA has deferred further efforts to derive national BAFs for methylmercury at this time. EPA notes, however, that there may be adequate field data for some waterbodies or geographical regions to derive, accurate predictive, site-specific methylmercury BAFs. EPA may reconsider developing national methylmercury BAFs in the future once more field data is available for a broader range of species and aquatic ecosystems, or once more information is available describing the mechanisms that affect bioaccumulation. Such information could enable EPA to more accurately predict methylmercury bioaccumulation on a broader scale given a certain total mercury concentration in water.

IV. Current Activities To Address Mercury Pollution

EPA is very aware of the multimedia character of mercury as an environmental contaminant. As has been discussed, releases of mercury are largely into the air, but releases directly into water and onto the land can also be significant. Moreover, statutory authority over mercury releases into various media are under the purview of all of EPA's statutes. To coordinate its various activities dealing with mercury, EPA issued a draft Mercury Action Plan for public comment in 1998 and expects to issue a revised Plan shortly. The Plan lays out a comprehensive program to address all aspects of the mercury problem from all sources and into all media, using all of the Agency's tools, and includes the issuance and implementation of this human health water-quality criterion. Some of the approaches currently employed to inform the public of the human health risks of mercury, and to manage, control, and reduce its release to the environment are briefly discussed below.

A. Fish Consumption Advisory Activities

States and authorized Tribes have primary responsibility for protecting residents from the health risks of consuming contaminated noncommercially caught fish and wildlife. They do this by issuing fish consumption advisories for the general population, recreational and subsistence fishers, as well as for sensitive subpopulations (such as pregnant women, nursing mothers, and children). These advisories inform the public that unacceptable concentrations of chemical contaminants (*e.g.,* methylmercury and dioxins) have been found in local fish and wildlife. The advisories include recommendations to limit or avoid consumption of certain fish and wildlife species from specific waterbodies or, in some cases, from specific waterbody types (*e.g.,* all lakes). States typically issue five major types of advisories and bans to protect both the general population and specific subpopulations. When levels of chemical contamination pose a health risk to the general public, States may issue a no consumption advisory for the general population. When contaminant levels pose a health risk to sensitive

subpopulations, States may issue a no consumption advisory for the sensitive subpopulation. In waterbodies where chemical contamination is less severe, States may issue an advisory recommending that either the general population or a sensitive subpopulation restrict their consumption of the specific species for which the advisory is issued. A commercial fishing ban can be issued, that prohibits the commercial harvest and sale of fish, shellfish, and/or wildlife species from a designated waterbody and, by inference, the consumption of all species identified in the fishing ban from that waterbody.

EPA has published guidance for States and Tribes to use in deriving their recommended fish consumption limits. See *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume 2* (USEPA, 2000e). That guidance addresses chemical contaminants with carcinogenic and/or noncarcinogenic effects, calculating consumption limits for a single contaminant in a multiple species diet or for multiple contaminants causing the same chronic health effects endpoints. The guidance recommends expressing species-specific consumption limits as fish meals per month, calculated at various fish tissue concentrations for both noncancer and cancer endpoints. Developing fish consumption limits requires making assumptions about the edible portions of fish because most chemical contaminants are not evenly distributed throughout the fish. The fish advisory guidance also recommends that human exposure via sources of contaminants other than consumption of recreationally or subsistence caught fish should be quantified.

B. Mercury Water Quality Standards

As discussed above, once EPA publishes new or revised section 304(a) water quality criteria guidance that reflects the 2000 Human Health Methodology, EPA expects States and authorized Tribes to reassess their water quality standards and, where necessary, establish new or revised water quality criteria consistent with one of the four approaches described above.

EPA has published numerous recommended water quality criteria for mercury throughout the years, reflecting changes in the best available scientific information. Consistent with CWA Section 303(c)(2)(B), States and authorized Tribes have adopted a numeric criterion, or an appropriate narrative translator, for mercury. Some States have adopted a previously recommended AWQC for aquatic life of 0.12 ng/L total mercury (USEPA, 1984). This value is based on a tissue residue value and bioconcentration factor and was derived using an aquatic life criteria methodology that was superceded by the 1985 aquatic life guidelines (Stephen *et al.,* 1985). EPA's promulgation of the National Toxics Rule in 1992 (see 40 CFR 131.36) included this value with an additional footnote directing States to measure methylmercury in the edible portion of aquatic species of concern, and initiate a revision of its criterion in water quality standards to protect designated uses, if the ambient water concentration exceeds 12 ng/L more than once in a three year period.

More recently, many States have adopted EPA's 1997 criteria recommendations of 50 ng/L total mercury for human health protection from the consumption water and organisms and 51 ng/L total mercury for human health protection from the consumption of organisms only. See 62 FR 42160. These value was derived using toxicological and exposure input values current at the time of its publication, including a bioconcentration factor. The criterion published today reflects EPA's 2000 Human Health Methodology, reflects the best available science, and supercedes all previous section 304(a) human health mercury criteria recommendations published by EPA, except for the waters of the Great Lakes System as discussed below. EPA encourages States and authorized Tribes to adopt the methylmercury criterion published today in their water quality standards to protect human health. States and authorized Tribes may alternatively develop data which indicates a site-specific water quality criteria for a particular pollutant is appropriate and take action to adopt such a criteria into their water quality standards. Site-specific criteria are allowed by regulation and are subject to EPA review and approval.

In 1995, EPA promulgated the *Final Water Quality Guidance for the Great Lakes System*. See 60 FR 15366, 40 CFR 132). This rule established a numeric criterion, based in part on bioaccumulation factors (BAFs) and a factor to account for other exposure sources, of 3.1 ng/L for total mercury in ambient waters of the Great Lakes System for human health protection. EPA continues to view this criterion as appropriately protective for these waters. Great Lakes States and authorized Tribes are also encouraged to adopt today's criterion for methylmercury in fish tissue in addition to the ambient water criterion for mercury contained in 40 CFR 132.

As discussed above, water quality standards consist of designated uses, water quality criteria to protect designated uses, an antidegradation policy, and general policies for application and implementation. States and authorized Tribes have considerable discretion in designating uses, and may find that changes in use designations are warranted. EPA reviews any new or revised use designation, including refinement of a designated use, adopted by States and authorized Tribes to determine if the standards meet the requirements of the CWA and implementing regulations. Under 40 CFR 131.10(j), a use attainability analysis (UAA) must be conducted whenever a State or authorized Tribe designates or has designated uses that do not include the uses specified in Section 101(a)(2) of the CWA (*i.e.,* suitable for fishing and swimming), or when the State wishes to remove a designated use that is specified in section 101(a)(2) of the Act, or adopt subcategories of uses that require less stringent criteria. Uses are considered by EPA to be attainable, at a minimum, if the uses can be achieved (1) when effluent limitations under Section 301(b)(1)(A) and (B) and Section 306 are imposed on point source dischargers, and (2) when cost effective and reasonable best management practices are imposed on nonpoint source dischargers. 40 CFR 131.10 lists grounds upon which to base a finding that attaining the designated use is not feasible, as long as the designated use is not an existing use.

States and authorized Tribes may also adopt water quality standards variances. EPA believes variances are particularly suitable when the cause of nonattainment is discharger-specific and/or it appears that the designated use in question will eventually be attainable. EPA has approved the granting of water quality standards variances by States in circumstances which would otherwise justify changing a use designation on grounds of nonattainability (*i.e.,* the six circumstances contained in 40 CFR 131.10(g)). In contrast to a change in standards which removes a use designation for a water body, a water quality standards variance can apply only to the discharger to whom it is granted and only to the pollutant parameter(s) upon which the finding of nonattainability was based; the underlying standard remains in effect for all other purposes.

The essential elements of a variance are: a variance should be granted only where there is a demonstration that one of the use removal factors (see 40 CFR

131.10(g)) has been satisfied; a variance is granted to an individual discharger for a specific pollutant(s) and does not otherwise modify the standards; a variance identifies and justifies the numerical criteria that will apply during the existence of the variance; a variance is established as close to the underlying numerical criteria as is possible; a variance is reviewed every three years, at a minimum, and extended only where the conditions for granting the variance still apply; upon expiration of the variance, the underlying numerical criteria have full regulatory effect; a variance does not exempt the discharger from compliance with applicable technology or other water quality-based limits; and, a variance does not affect effluent limitations for other dischargers.

In l995, EPA and the Great Lakes states agreed to a comprehensive plan to restore the health of the Great Lakes. Using the *Final Water Quality Guidance for the Great Lakes System* (see 40 CFR 132), Great Lakes States and authorized Tribes established water quality criteria, methodologies, policies and procedures to establish consistent, enforceable, long term protection for fish and shellfish in the Great Lakes and their tributaries, as well as the people and wildlife who consume them. Under 40 CFR 132, the State of Ohio adopted, and EPA approved, a statewide variance specifically for mercury.

The basis for this mercury variance was the adverse social and economic impacts of end of pipe treatment to attain effluent limits for mercury of less than 12 ng/L total mercury. Ohio determined a cost of $10 million per pound for mercury removal from NPDES permitted discharges. Ohio also specified implementation procedures whereby the discharger requests coverage under the mercury variance; describes the mercury control measures taken to date; provides a plan of study intended to identify and control sources of mercury (including documenting current influent and effluent concentrations, identifying known sources, describing how known sources will be reduced or eliminated, identifying other potential sources, and providing a schedule for evaluating sources and control methods); and, provides an explanation of the permittee's basis for concluding that there are no readily available means of complying without resorting to end of pipe treatment. Where the discharger demonstration is inadequate (including an inadequate demonstration that end of pipe treatment is the only readily available option for complying), Ohio denies the applicability of the mercury variance to the individual discharge. In this case, each variance is also submitted to EPA for review and action.

It is important to note that Ohio's mercury variance relieves individual dischargers of the responsibility to demonstrate social and economic impacts of complying with the mercury criteria. Individual dischargers must still demonstrate that end of pipe treatment is the only viable compliance option. In addition, in this case EPA retains review and approval authority over individual variance decisions, but EPA's review is limited to the technical merits of the alternatives analysis (*e.g.,* are there options other than end of pipe treatment).

C. Total Maximum Daily Load

Section 303(d) of the CWA requires States and authorized Tribes to identify and establish a priority ranking for waters for which existing pollution controls are not stringent enough to attain and maintain applicable water quality standards; to establish total maximum daily loads (TMDLs) for those waters; and to submit from time to time the list of waters and TMDLs to EPA. Section 303(d) of the CWA requires EPA to review and approve or disapprove lists and TMDLs within 30 days of the date they are submitted. If EPA disapproves a State's or Tribe's identification of waters or a TMDL, EPA must establish the list or a TMDL for the State or authorized Tribe.

TMDLs specify the amount of a particular pollutant that may be present in the water and still allow the waterbody to meet applicable water quality standards, including a margin of safety and after considering seasonal variability. TMDLs allocate the allowable pollutant loads among point and nonpoint sources of pollution. TMDLs also provide the basis for attaining or maintaining applicable water quality standards through implementation of pollutant reductions in the NPDES permit program and in nonpoint source controls programs.

On the 1998 lists of impaired waterbodies, 33 States reported at least one waterbody as being impaired due to mercury contamination. Over 1,000 individual waterbody segments were identified by the States as specifically having mercury contamination. In addition, over 3,900 waterbody segments were identified as impaired due to contamination by metals, which may include mercury.

In many cases, as described earlier in this document, atmospheric deposition can be a significant source of mercury to waterbodies. On the 1998 lists of impaired waters, atmospheric deposition of mercury was identified as a source of impairment in over 600 waterbody segments. As States are not required to identify atmospheric deposition as a source of impairment, this is likely to be an underestimate.

EPA is currently conducting pilot studies to assist States in developing TMDLs for waterbodies impaired by mercury from atmospheric deposition. One goal of the pilot studies is to evaluate modeling approaches, such as techniques for identifying the relative contribution of various types of mercury sources to a waterbody. Another goal of the studies is to examine how TMDLs can incorporate ongoing efforts to address sources of mercury, pollution including programs under the Clean Air Act and water-related pollution prevention activities.

D. Pollution Minimization Activities

The CWA prohibits the discharge of any pollutant (other than dredged of fill material) from a point source into waters of the United States except in compliance with an NPDES permit. See section 301(a) and section 402 of the CWA. NPDES permits are issued by EPA or by States and Tribes that are authorized to administer the NPDES program. These permits commonly contain numerical limits on the amounts of specified pollutants that may be discharged. In place of or in addition to numerical limits, permits may contain best management practices (BMPs) (*e.g.,* practices or procedures that a facility installs or follows that result in a reduction of pollutants to waters of the United States). These ''effluent limitations'' implement both technology-based and water quality-based requirements of the Act. Technology-based effluent limitations represent the degree of control that can be achieved by point sources using various levels of pollution control technology. See sections 301, 304, and 306 of the CWA For a publicly owned treatment works (POTW), section 301(b)(1)(B) of the CWA specifies the applicable technology-based control standard as ''secondary treatment.'' See CWA sections 301(b)(1)(B).

As discussed above, the CWA directs the States to establish water quality standards. See CWA section 303(c). If necessary to achieve applicable water quality standards, NPDES permits must contain water quality-based limitations (WQBELs) more stringent than the applicable technology-based requirements. See CWA section 301(b)(1)(C). The need for a WQBEL is based on a determination that pollutants in a discharger's effluent will cause, have the reasonable potential to cause,

or contribute to a violation of the applicable water quality standards. See 40 CFR 122.44(d)(1).

Many point source dischargers of mercury have either technology-based limits or water quality-based limits for mercury in their NPDES permits. Many point source dischargers install treatment technologies that will treat their effluent, resulting in lower quantities of mercury in their discharged effluent. In addition, point sources that discharge mercury to the Great Lakes System are required to develop a pollutant minimization program (PMP) for mercury whenever their WQBELs for mercury are calculated to be less than the quantification level of the applicable analytical method. See 40 CFR 132, Appendix F, Procedure 8.D. Implementation of PMPs should be viewed as an iterative process as new and improved methods to reduce or eliminate mercury become available, including a control strategy which identifies control measures to be implemented that become enforceable requirements in their NPDES permit. These PMPs are subject to revision as the implementation of PMPs is viewed as an iterative process recognizing that there will be new and improved methods to reduce or eliminate mercury that are not currently available.

Some pollution prevention strategies focus on changing existing processes or replacing uses of mercury in production activities with alternative substances as a way of achieving water quality-based effluent limitations. Also, some facilities with mercury do not discharge mercury to waters of the United States, but rather transport the waste to hazardous waste disposal facilities or incinerate it. EPA expects mercury dischargers to use one or a combination of these approaches to reduce or eliminate discharges of mercury to the environment. Pollution prevention, however, is the preferred approach because it reduces mercury releases to the environment in general.

E. National Air Emissions Regulations

Most of the mercury currently entering the United States environment is the result of air emissions of mercury that are deposited on land or water. In addition to publishing mercury water quality criteria guidance under the Clean Water Act, under the Clean Air Act EPA has issued a number of regulations to reduce mercury pollution through air emissions. The following summarize the key regulations pertaining to air sources of mercury.

—Municipal waste combustors emitted about 20 percent of total national mercury emissions into the air in 1990. EPA issued final regulations for municipal waste combustors in 1995. These regulations are predicted to reduce mercury emissions from these facilities by about 90 percent from 1990 emission levels.

—Medical waste incinerators emitted about 24 percent of total national mercury emissions into the air in 1990. EPA issued emission standards for medical waste incinerators in 1997. When fully implemented, the final rule is expected to reduce mercury emissions from medical waste incinerators by about 94 percent from 1990 emission levels.

—Hazardous waste combustors emitted about 2.5 percent of total national mercury emissions in 1990. In February 1999, EPA issued emission standards for these facilities, which include incinerators, cement kilns, and light weight aggregate kilns that burn hazardous waste. When fully implemented, these standards are predicted to reduce mercury emissions from hazardous waste combustors by more than 50 percent from 1990 emission levels.

In addition to the above regulations, EPA is developing a regulation that will limit mercury emissions from chlorine production plants. Proposed and final rules are scheduled for late 2000 and 2001, respectively. Under the Integrated Urban Air Toxics Strategy, which was published in 1999, EPA is developing emissions standards for categories of smaller sources of air toxics, including mercury, that pose the greatest risk to human health in urban areas. These standards are expected to be issued by 2004.

Also, on December 14, 2000 EPA announced that it intends to develop a regulation to limit mercury emissions from coal-fired power plants. A proposal is expected in late 2003 and a final regulation at the end of 2004. These plants are the largest source of mercury emissions in the United States of mercury emissions from coal-fired power plants will be a significant next step in this ongoing effort to address mercury emissions.

V. Derivation of the Methylmercury Fish Tissue Water Quality Criterion

A. What Is the Health Risk Assessment for Methylmercury?

Methylmercury is highly toxic to mammalian species and causes a number of adverse effects. There are no data to indicate that it is carcinogenic in humans, and it induces tumors in animals only at highly toxic doses. The quantitative health risk assessment for a non-carcinogen is a reference dose (RfD). This is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious health effects during a lifetime. EPA has revised the current RfD for methylmercury. The value of the RfD has not changed from 0.1 μg/kg/day, but the basis for the RfD has been updated using the most current data and analyses. This RfD is protective of all populations in the United States, including sensitive subpopulations. It is applied to lifetime daily exposure as are other RfDs. The basis for the RfD update is discussed below.

EPA previously published two RfDs for methylmercury representing the Agency's views at the time. An RfD of 0.3 μg/kg/day was established in 1985 and published on EPA's Integrated Risk Information System (IRIS) in 1986. The critical effects were multiple central nervous system (CNS) effects, including ataxia (problems with muscle co-ordination) and paresthesia (changes in the sense of touch) in Iraqi adults who had eaten methylmercury-contaminated grain (summarized by Clarkson *et al.,* 1976; Nordberg and Strangert, 1976; and WHO, 1976).

An RfD of 0.1 μg/kg/day was established as the Agency consensus estimate in 1995. It was published in IRIS in 1996 and in extended form in 1997 in the Mercury Study (which included a state-of-the-science evaluation of the health effects of methylmercury). Prior to the 1997 Mercury Study, many scientists and other concerned parties had questioned whether the 1985 RfD based on effects in exposed adults was protective against developmental effects. The 1995 RfD was thus set on clinical neurological signs and symptoms in 81 Iraqi children who had been exposed when their mothers ate methylmercury-contaminated grain while pregnant. Maternal hair mercury was the indication of exposure. EPA used a mathematical procedure, calculation of a benchmark dose (BMD), to estimate the functional equivalent of a no adverse effect level from the data. A one compartment pharmacokinetic model was used to determine an amount of daily methylmercury ingestion which would result in the BMD. An uncertainty factor of 10 was applied to deal with the following areas of uncertainty and variability: Wide variation in half-life of methylmercury in the body and the variation that occurs in the hair-to-blood ratio for mercury; lack of a two-generation reproductive study; and lack of data on possible

chronic manifestations of the adult effects.

Since 1997 there has been continuing discussion in the scientific community as to regarding the level of human exposure to methylmercury that is likely to present no appreciable risk of adverse health effects. Congress directed EPA through the House Appropriations Report for FY99 to contract with the National Research Council (NRC) to evaluate the data on the health effects of methylmercury, with emphasis on data available after the 1997 Mercury Study. NRC was to provide recommendations on issues relevant to the derivation of an appropriate RfD for methylmercury. EPA received the NRC report *Toxicological Effects of Methylmercury* in July, 2000 (NRC, 2000). EPA has thoroughly reviewed this document and generally concurs with the NRC findings and recommendations. Based on the NRC report, EPA has revised the RfD for methylmercury. A draft EPA RfD document was submitted for external scientific review in late October 2000; at the same time it was circulated for comment to other Federal Agencies through the Committee on Environment and Natural Resources (CENR) and Office of Science and Technology Policy (OSTP). See the **ADDRESSES** section of this Notice to obtain a copy of the RfD peer review report from the Water Docket. A public scientific review meeting was held November 15, 2000; the final peer review report was delivered to EPA on December 7, 2000. See the **ADDRESSES** section of today's Notice to inspect the peer review report in the Water Docket. The draft RfD document was revised to reflect the scientific critique received from the peer review, and it is now available as the risk assessment chapter in the water quality criterion document for methylmercury.

The revised RfD was derived to be protective of the population (including sensitive subgroups) against the many adverse health effects associated with methylmercury exposure. Most data are on neurotoxicity, particularly in developing organisms; there is a substantial amount of data on effects of methylmercury on human development. The brain is considered to be the most sensitive target organ for which there are data suitable for derivation of an RfD.

The NRC report and EPA's review considered human epidemiological, longitudinal developmental studies from the Seychelles Islands, the Faroe Islands, and New Zealand in assessing the quantitative risk from mercury exposure. These are all studies wherein effects were measured in children of mothers exposed to methylmercury through consumption of fish and seafood. The Seychelles study showed no evidence of impairment related to methylmercury exposure, while both the Faroe Islands and New Zealand studies found dose-related adverse effects on a number of neuropsychological endpoints. The Faroe Islands study is the larger of the latter two studies and has been extensively peer reviewed. EPA has used the Faroe Islands study for derivation of the RfD. A BMD was chosen as the most appropriate method of quantifying the dose-effect relationship. The BMD EPA used is the lower limit (BMDL) on a 5% effect level obtained by applying a K power model ($K \geq 1$) to dose-response data based on mercury measured in cord blood.

There are several endpoints which are sensitive measures of methylmercury effects in the Faroese children. EPA considered the recommendations of the NRC and our external peer review panel in coming to a decision as to the appropriate endpoint. The NRC recommended the use of a BMDL of 58 ppb mercury in cord blood from the Boston Naming Test (BNT). This is a test in which the subject is shown drawings and is asked to name what they depict. The BNT score is related to language ability, assessing word formulation and word retrieval. NRC considered the score from the whole cohort to be the most sensitive, reliable endpoint. The NRC noted that the scores for the Continuous Performance Test (CPT) gave a lower BMDL, 46 ppb mercury in cord blood, but that these results were from a smaller number of children (there had been test administration problems in one year of the study).

The external peer panel disagreed with the NRC choice. They felt that the BNT scores showed an effect of concomitant PCB exposure in some analyses. They preferred a PCB-adjusted BMDL of 71 ppb mercury in cord blood for the BNT. A difficulty with this choice is that this BMDL is based on scores from only about one-half of the total cohort.

EPA prepared a comparison of the NRC and peer reviewer recommended approaches; this analysis also includes BMDLs from mercury-associated Faroese endpoint, results of the NRC integrated analysis and geometric means of four scores from the Faroes. The table of comparisons can be found in the methylmercury water quality criterion document. When one completes the dose conversion and applies an uncertainty factor (see paragraphs below), the calculated RfD values converge at the same point: 0.1 μg/kg/day. Rather than choosing a single measure for the RfD critical endpoint, EPA considers that this RfD is based on several scores. These test scores are all indications of neuropsychological processes which are involved with the ability of a child to learn and process information. In the *Water Quality Criterion for the Protection of Human Health: Methylmercury*, EPA uses the NRC recommended BMDL of 58 ppb mercury in cord blood as an example in the dose conversion and RfD calculation.

The BMDL of 58 ppb mercury in cord blood was converted to an ingested daily dose using a one-compartment pharmacokinetic model similar to that used in the Mercury Study. The ingested daily dose at the benchmark dose is 1 μg/kg per day.

In the water quality criterion guidance for methylmercury, EPA discusses several sources of variability and uncertainty in its estimate and chose an uncertainty factor of 10. This was based on a factor of 3 for pharmacokinetic inter-individual variability (particularly methylmercury half-life and uncertainty concerning the relationship between cord and maternal blood mercury concentrations). An additional factor of 3 was applied for pharmacodynamic variability and uncertainty. EPA also describes additional areas of concern including inability to quantify long-term sequelae; concern for effects that may be observed at exposures below the BMDL; and lack of a two-generation reproductive effects assay. Given the over all robustness of the data base for methylmercury, EPA considered that a composite uncertainty factor of 10 was sufficient; this conclusion was affirmed by the external peer review panel.

The resulting RfD for methylmercury is, thus, 0.1 μg/kg per day. This RfD is applied to lifetime daily exposure for all populations in the United States, including sensitive subpopulations.

B. How Are Mercury Exposure and Relative Source Contribution Assessed?

The exposure assessment and estimate of the relative source contribution (RSC) for methylmercury follows the recently published 2000 Human Health Methodology. When an AWQC is based on noncarcinogenic effects, anticipated exposures from sources other than drinking water and freshwater/estuarine fish and shellfish ingestion are taken into account so that the entire RfD is not apportioned to drinking water and freshwater/estuarine fish and shellfish consumption alone. The amount of exposure attributed to each source compared to total exposure is referred to as the RSC. The RSC is

used to adjust the RfD to ensure that the water quality criterion is protective enough, given the other anticipated sources of exposure. Detailed discussion of the RSC method is described in the 2000 Human Health Methodology.

The method of determining the RSC differs depending on several factors: (1) The magnitude of total exposure compared with the RfD; (2) the adequacy of data available; (3) whether more than one criterion is to be set for methylmercury; and (4) whether there is more than one significant exposure source for the chemical and population of concern. The population of concern, sources of methylmercury exposure, and estimates of exposure and the RSC for the identified population are discussed in detail in the 2001 methylmercury water quality criterion document.

The population basis for the exposure estimate are adults in the general population. The health risk measure, the RfD, is intended to be protective of the whole population, including sensitive subpopulations. This is not a developmental RfD *per se*; even though the critical endpoint was neurotoxic effects observed in children, application of the RfD is not restricted to pregnancy only, or to developmental periods only.

The exposure assessment section of the 2001 methylmercury water quality criterion document characterizes the sources of methylmercury exposure in environmental media, provides available information on levels of occurrence, and provides estimates of intake from the relevant sources. Specifically, the evaluation includes estimates of methylmercury in ambient surface water, drinking water, fish, non-fish foods, air, soil and sediment.

As discussed in the 2000 Human Health Methodology, the Agency's RSC policy approach allows for use of a subtraction method to account for other exposures when one health-based water quality criterion is relevant for the chemical in question. In this circumstance, other sources of exposure can be considered ''background'' and can be subtracted from the RfD. Such is the case with methylmercury; that is, there are no health-based criteria, pesticide tolerances, or other regulatory activities to apportion with the alternate percentage approach (see discussion in the 2000 Human Health Methodology).

The assessment of human exposure in the methylmercury water quality criterion document includes estimates from multiple media sources. Based on available data, human exposures to methylmercury from all media sources except freshwater/estuarine and marine fish are negligible, both in comparison to exposures from fish and compared to the RfD. Estimated exposure from ambient water, drinking water, non-fish dietary foods, air, and soil are all, on average, at least several orders of magnitude less than those from freshwater/estuarine fish and shellfish intakes. In units of μg/kg-day, non-fish sources of intake are in the range of 10^{-5} to 10^{-9} μg/kg-day for adults in the general population (USEPA, 2001). The combined methylmercury exposure intakes from water ingestion, non-fish diet, air, and soil represent approximately 0.07 percent of total estimated exposure to methylmercury (less than 1/100 of one percent of the RfD). Therefore, these exposures were not factored into the RSC.

Ingestion of marine fish is a significant contributor to total methylmercury exposure. This intake has been accounted for in the derivation of the fish tissue water quality criterion value. The estimate of marine fish methylmercury exposure is based on data available primarily from the National Marine Fisheries Survey. See the exposure section of the 2001 methylmercury water quality criterion document. Species-specific mean concentrations of methylmercury in marine fish and shellfish were used to estimate daily exposure from methylmercury. A consumption-weighted mean concentration of methylmercury for all marine fish and shellfish was then calculated by EPA (USEPA 2001) based on the mean consumption rates from the *United States Department of Agriculture's Continuing Survey of Food Intake by Individuals (CSFII) 1994–1996* (USDA 1998). The CSFII 1994–1996 consumption rates are also the source of EPA's recommended intake rates for freshwater/estuarine fish. Detailed discussion of this procedure is included in the methylmercury water quality criterion document (USEPA, 2001). Following the Mercury Study (USEPA, 1997a), 100 percent of the mercury in marine fish was assumed to be present as methylmercury. The estimated weighted-average methylmercury concentrations in marine fish is 0.157 mg methylmercury/kg fish tissue, and the estimated average exposure to methylmercury from marine fish is 2.7×10^{-5} mg methylmercury/kg fish tissue-day. This exposure represents almost 30 percent of the RfD.

As indicated above, the RSC from marine fish has been calculated with an assumed average intake of 12.46 gm/day of marine fish based on the CSFII, for all respondents aged 18 and over. The Mercury Study (USEPA, 1997a) indicates that in the general population of fish consumers, those that consume freshwater/estuarine species of fish are also consumers of marine species of fish and shellfish. EPA has, therefore, made the same assumption in the derivation of the methylmercury fish tissue residue water quality criterion. EPA's recommended default fish intake rate to protect the general population of consumers of freshwater/estuarine fish is 17.5 grams/day. This value is the 90th percentile from the CSFII 94–96 survey (USEPA, 2000f). As described in the 2000 Human Health Methodology, the Agency selected this default intake rate as protective of a majority of the population. The recommended body weight for the general adult population used in this estimate is 70 kg (USEPA, 2000a). While EPA acknowledges that consumers of freshwater/estuarine fish are also typically consumers of marine fish, EPA does not believe that the high-end consumer of freshwater/estuarine fish is also a high-end consumer of marine fish. EPA believes that it is more appropriate, and a reasonably conservative assumption, to use a central tendency intake rate (approximately 12.5 grams/day) for the marine fish component of the RSC estimate.

For deriving the fish tissue water quality criterion for methylmercury, the mean daily exposure estimate from ingestion of marine fish for adult consumers in the general population (which is also protective of the developmental endpoint), 2.7×10^{-5} mg/kg-day, is used for the RSC in the subtraction approach to calculate the methylmercury fish tissue water quality criterion.

C. How Is the Methylmercury Water Quality Criterion Calculated?

The derivation of a methylmercury water quality criterion requires a human health risk assessment (*e.g.,* an RfD), exposure data (*e.g.,* the amount of pollutant ingested or inhaled per day), and data about the target population to be protected. The equation for calculating the methylmercury fish tissue residue water quality criterion for the protection of human health is:

$$TRC = \frac{BW \times (RfD - RSC)}{\sum_{i=2}^{4} FI_i}$$

Where:

TRC = Fish tissue residue criterion (mg methylmercury/kg fish tissue) for freshwater and estuarine fish and shellfish

RfD = Reference Dose (based on noncancer human health effects). For methylmercury it is 0.0001 mg/kg BW-day (0.1 μg/kg BW-day)

RSC = Relative source contribution (subtracted from the RfD to account for marine fish consumption) estimated to be 2.7×10^{-5} mg/kg BW-day

BW = Human body weight default value of 70kg (for adults)

FI = Fish intake at trophic level (TL) i (i = 2, 3, 4); total default intake is 0.0175 kg fish/day for general adult population. Trophic level breakouts for the general population are: TL2 = 0.0038 kg fish/day; TL3 = 0.0080 kg fish/day; and TL4 = 0.0057 kg fish/day.

This equation is the same equation used in the 2000 Human Health Methodology to calculate a water quality criterion for a noncarcinogenic pollutant, but is rearranged to solve for a protective concentration in fish tissue rather than in water. Thus, it does not include a BAF or drinking water intake value (as discussed above, exposure from drinking water is negligible). When all of the numeric values are put into the generalized equation, the Tissue Residue Criterion = 0.3 mg methylmercury/kg fish (rounded to one significant digit from 0.292 mg methylmercury/kg fish tissue). This is the concentration in fish tissue that should not be exceeded based on a total fish and shellfish consumption-weighted rate of 0.0175 kg fish/day (17.5 g/day). On a site-specific or local level, States and authorized Tribes can chose to apportion all of the 0.0175 kg fish/day to the highest trophic level consumed for their population or modify it based on local or regional consumption patterns. EPA strongly encourages States and authorized Tribes to develop a water quality criterion for methylmercury using local or regional data over the default values if they believe that such a water quality criterion would be more appropriate for their target population.

VI. How Can the Fish Tissue Residue Water Quality Criterion Be Related to a Mercury Concentration in Water?

EPA recognizes that a State's water quality criterion in the form of a fish tissue residue value may pose implementation challenges under traditional water quality based control programs. Under a water quality-based approach to controlling pollutants, NPDES permit compliance with water quality standards is usually determined by comparing the allowable concentration of a pollutant in the water column to the actual pollutant concentration measured in the water column over some specific period of time. Mechanisms to control pollutants in waterbodies usually involve determining the allowable discharge load to a waterbody by conducting TMDL and waste load allocation (WLA) calculations. The traditional approach for monitoring, measuring compliance, and ultimately controlling the discharge of a pollutant is based on the concentration of the pollutant in water; thus, a mechanism is needed to relate concentrations of methylmercury in fish tissue to concentrations in water. EPA has provided three recommended approaches in order to relate the methylmercury fish tissue water quality criterion to concentrations of mercury in water. Each approach has its own advantages, limitations, and uncertainties as discussed below.

EPA's preferred approach for relating a concentration of methylmercury in fish tissue to a concentration of mercury in ambient water is to derive site-specific BAFs based on water and fish collected in the waterbody of concern. This recommendation is consistent with EPA's bioaccumulation guidance contained in the 2000 Human Health Methodology. Furthermore, this recommendation is consistent with the views expressed by the methylmercury BAF peer reviewers. See the Addresses section of today's Notice to obtain peer review responses from the Water Docket. EPA prefers the use of site-specific BAFs because they inherently incorporate the net effects of the biotic and abiotic factors at a particular location that can affect bioaccumulation in the aquatic food chain, and thus provide an accurate accounting of the uptake of methylmercury. When sampling fish and water to derive a site-specific BAF, one needs to consider how best to sample so that issues such as seasonal variability in fish exposure to methylmercury, spacial variability, and fish size are taken into account. These issues and others should also be assessed in relation to the fish consumption patterns of the exposed human population. EPA expects to publish specific guidance for deriving field-measured site-specific BAFs in late 2001. However, until then the recently published procedures in the 2000 Human Health Methodology for deriving BAFs can be used as a general guide. In addition, the *Bioaccumulation Technical Support Document* (TSD) for the 2000 Human Health Methodology (expected to be published in late 2001) will provide additional information and guidance on deriving site-specific BAFs.

Another approach for deriving methylmercury BAFs is to use a bioaccumulation model. Most bioaccumulation models are generally process-based or mechanistic type mathematical models that are meant to represent what occurs in nature. At this time, the general science of bioaccumulation modeling, especially for mercury, is not advanced to the stage where models are readily available and applicable to all types of pollutants and aquatic systems. Three examples of mechanistic-type bioaccumulation models are: the Mercury Cycling Model (Tetra Tech, 1999); EPA's aquatic food chain model AQUATOX (USEPA, 2000g); and the Quantitative Environmental Analysis food chain model QEAFDCHN (QEA, 2000). There are only a few models that might be used to predict methylmercury bioaccumulation. Such models generally have not been widely used and have only been applied to mercury in a few aquatic ecosystems under specific environmental conditions. Of the examples listed above, only the Mercury Cycling Model was developed solely for mercury. The others have been generally developed for nonionic organic chemicals that bioaccumulate. They might be applied to mercury with substantial modifications. Most bioaccumulation models are based upon a chemical mass balance approach for fish or other aquatic organisms, which requires considerable understanding of mercury loadings to the environment and how mercury moves through the environment. Each model results in a BAF with some level of uncertainty. None of the example models can predict bioaccumulation without considerable site-specific information and at least some degree of calibration to the waterbody of interest, and in some cases considerable modification of the model. The amount and quality of data required for proper model application may equal or exceed that necessary to develop a site-specific methylmercury BAF. Other types of models could also be used if they are scientifically defensible. Regardless of the type of model, if a model is chosen, the issues discussed in the bioaccumulation guidance contained in the 2000 Human Health Methodology should be carefully considered. The derivation of site-specific parameters used in the model should also be documented, and some indication given of the uncertainty surrounding the BAFs predicted by the model.

EPA acknowledges that derivation of site-specific field-measured BAFs may not be feasible in all situations. Therefore, in the absence of site-specific methylmercury bioaccumulation data, a possible third approach is to use EPA's empirically derived draft methylmercury BAFs. As previously discussed, as part of initial efforts to

derive a water column-based section 304(a) water quality criterion, EPA used the Agency's BAF guidance in the 2000 Human Health Methodology and BAF methods in Volume III, Appendix D of the Mercury Study to develop draft empirically derived BAFs from field data collected across the United States and reported in the open literature. The empirically derived BAFs are listed by trophic level in Table 1.

TABLE 1.—EMPIRICALLY DERIVED BAFS FOR METHYLMERCURY

	BAF trophic level 2	BAF trophic level 3	BAF trophic level 4
BAF	160,000	680,000	2,700,000

The BAF peer reviewers expressed concerns about the predictive capability of these draft BAFs and about using them to derive a section 304(a) water quality criterion for methylmercury that would be accurately protective for waterbodies across the nation. However, EPA believes that the methylmercury BAFs in Table 1 are sufficiently predictive of bioaccumulation to be used in implementing a fish tissue based methylmercury water quality criterion in a State's or authorized Tribe's water quality standards in the absence of any other site-specific bioaccumulation data. Thus, EPA will consider water quality standards implementation approaches that use these empirically derived BAFs. EPA recognizes that these methylmercury BAF values are not entirely representative of the methylmercury bioaccumulation potential in all waterbodies across the United States, and they may over- or underestimate site-specific bioaccumulation potential. There is uncertainty in using these BAFs as they collapse a very complex nonlinear process into a simplistic and linear approach to predicting bioaccumulation and assume that the biotic and abiotic process affecting mercury fate and bioaccumulation are similar across different waterbodies. The decision to publish these empirically derived BAFs is an Agency risk management decision made based on the need for a mechanism to relate a fish tissue concentration of methylmercury to a water column concentration. EPA has selected the geometric mean of the field-measured BAFs obtained from the open literature as the empirically derived BAFs for each trophic level. EPA believes the geometric mean is the central tendency value that best represents the wide range of environmental and biological conditions present in the waters of the United States. Choosing a value near the extremes of the distribution (*e.g.*, 10th or 90th percentile) may introduce an unacceptable level of uncertainty into the CWA goal of protecting public health. Furthermore, EPA believes a geometric mean is most appropriate because the underlying processes of methylmercury bioaccumulation are more likely multiplicative than additive.

Other empirical, modeling, or newly developed bioaccumulation prediction approaches may be used to relate concentrations of methylmercury in fish tissue to concentrations of methylmercury in water, provided the approach is scientifically defensible and adequately documented.

In addition to using BAFs to relate concentrations of methylmercury in fish tissue to methylmercury concentrations in water, a factor is needed to translate methylmercury in water to its total mercury equivalent. NPDES permits and other water quality-based pollution control activities are traditionally based on the total concentration of the inorganic metal form, not the dissolved organic form. Many of the issues surrounding the uncertainty in predictability and transferability of methylmercury BAFs across different waterbodies also pertain to relating methylmercury in water to a given total mercury concentration. As with BAFs, EPA's preferred approach for translating between total and methylmercury is for States and authorized Tribes to measure total mercury and methylmercury and in the waterbody of interest. However, EPA will consider standards implemented with empirically derived translators. As part of exercise to develop draft methylmercury BAFs, EPA derived methylmercury-to-total mercury translator factors for rivers/streams and lakes. Like the BAFs, the methylmercury-to-total mercury translators were empirically derived based on water data collected in the field from a variety of locations across the United States. Depending on the available mercury water data, more than one translation may be necessary to translate to the total concentration of mercury in ambient waters. Table 2 lists the translator factors that could be used to translate between methylmercury and mercury in ambient surface waters in the absence of any site-specific data.

TABLE 2.—SUMMARY OF MERCURY TRANSLATORS

Translation	Lakes and reservoirs [1]	Rivers and streams [1]
Fraction of total mercury that is dissolved	0.60	0.37
Fraction of total mercury that is dissolved methylmercury	0.032	0.014
Fraction of total methylmercury that is dissolved methylmercury	0.61	0.49

[1] Values are from Section II, Table 15, of the EPA internal draft report *National Bioaccumulation Factors for Methylmercury,* available from the Water Docket.

VII. What Is the Relationship Between Fish Advisories and the Fish Tissue Residue Water Quality Criterion?

A majority of States and authorized Tribes with fish advisory programs have adopted a risk-based approach to developing fish advisories that is similar to the approach recommended in EPA's *Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories* (EPA 2000 e, h). However, due to variations in State and Tribal fish advisory programs, some States and Tribes may not be adequately warning the public of health risks. A small number of States continue to use fish consumption advisory approaches that are considered by EPA to be inadequate for protecting public health. The use of these approaches may lead to significant

increased health risks for people consuming fish harvested from contaminated local waters. Such approaches include the inappropriate use of Action Levels and Tolerances developed by EPA and the Food and Drug Administration. These are appropriate for use in the commercial market place, but are considered to be inappropriate for establishing local advisory needs and should not be used for that purpose.

Both today's section 304(a) human health water quality criterion guidance for methylmercury and EPA's recommended fish consumption limit for mercury (which EPA encourages States and authorized Tribes to use as guidance in setting fish advisories) are meant to protect humans from consumption of mercury-contaminated fish. The procedures for deriving these two values are consistent with each other, but in deriving the section 304(a) methylmercury water quality criterion, EPA used an RSC of 2.7 10^{-5} mg/kg-day to account for exposure from non-freshwater and non-estuarine fish. See section IV.B of today's Notice. The guidance for setting fish consumption limits (USEPA, 2000e) also discusses using an RSC to account for exposures other than noncommercially caught fish, but does not specifically require this to be done. The RSC guidance in the 2000 Human Health Methodology provides more detail and specific quantitative procedures to account for other exposure pathways. EPA recommends that States and authorized Tribes consider using an RSC to account other sources of mercury exposure when deriving a fish consumption limit and setting a fish advisory for mercury.

VIII. How Does EPA Suggest Implementing the Methylmercury Water Quality Criterion?

EPA encourages States and authorized Tribes to adopt the fish tissue residue water quality criterion for methylmercury outlined in this notice into their water quality standards to protect CWA section 101(a) designated uses related to human consumption of fish. This recommended water quality criterion reflects the most current and best science. EPA recognizes and emphasizes that States and authorized Tribes will need additional, specific procedures and water quality program guidance in order to implement water quality criteria they adopt based on this guidance. These procedures include, but are not necessarily limited to: (1) An analytical method for detecting and measuring concentrations in fish and water; (2) a field sampling plan for collecting fish and protocols for laboratory analysis and data interpretation; (3) a procedure for translating methylmercury concentrations in fish to total mercury concentrations in ambient surface water or effluent; (4) data quality objectives and associated procedures for determining attainment of the water quality criterion and status of designated use impairment based on fish residue data; (5) harmonization with fish consumption advisory programs, (6) procedures for determining the need for a water quality-based effluent limit (WQBEL) in NPDES permits for point source discharges of mercury; (7) procedures for developing and implementing WQBELs for NPDES permits; and, (8) procedures for developing targets for TMDL load and waste load allocations.

To help States and authorized Tribes adopt the recommended section 304(a) water quality criterion for methylmercury as part of their standards, and to implement those standards, EPA plans to begin development implementation procedures and guidance documents by the end of 2001. These will be part of a broad national implementation policy for this water quality criterion. The implementation policy will be developed with consideration of the draft Mercury Action Plan submitted for public comment in 1998 and expected to be revised soon. EPA expects States and authorized Tribes to adopt new or revised human health mercury water quality criteria and to use the procedures and guidance contained in the forthcoming implementation policy to adopt their water quality criteria within five years from today's publication. EPA generally believes that five years from the date of EPA's publication of new or revised section 304(a) water quality criteria guidance is a reasonable time by which States and Tribes should take action to adopt new or revised water quality criteria necessary to protect the designated uses of their waters. See 63 FR 68353.

EPA recently published a new analytical method (method 1631) for detecting and measuring total and dissolved mercury in water and fish samples (USEPA, 1999b). This method is approximately 400 times more sensitive than EPA's previously recommended analytical method and is capable of measuring mercury concentrations well into the ranges identified in this notice for fish concentrations as well as those anticipated for associated water concentrations (detection limit of 0.2 ng/L in water). This method determines the amount of total mercury, not methylmercury, in water and fish. This will likely result in a substantial increase in the number of point source discharges of mercury needing WQBELs in their NPDES permits.

Among the many issues associated with implementation, State and Tribal water quality managers will need to identify which species to target for sampling, determine sample compositing procedures and frequency of sampling, and relate sampling and analysis procedures to the consumption patterns intended for protection by the water quality criterion. The Agency has published guidance on field sampling and analysis as part of the package of guidance to States and Tribes for issuing fish consumption advisories. EPA anticipates that this guidance will also be useful for implementing State or Tribal water quality criterion for methylmercury based on today's criterion guidance.

Three translations are necessary to relate the methylmercury water quality criterion for fish tissue expressed in this notice to a total mercury concentration in ambient water or effluent, for NPDES or TMDL purposes. The first translation is to determine the fraction of measured mercury in fish that is methylmercury. Although this can vary in practice, the methylmercury fraction is typically very high in freshwater and estuarine fish, and approaches 100 percent for higher trophic level organisms. The second translation is from methylmercury in fish to methylmercury in water. As discussed in detail above, the best means of determining this relationship is through site-specific analysis of bioaccumulation patterns. The third translation is from methylmercury in water to total mercury in water. As with the BAFs, the preferred method to do this translation is to measure the concentrations of methylmercury and total mercury in ambient water.

As mentioned, EPA believes an implementation policy is necessary that addresses recommendations for establishing sampling protocols and determining attainment of State or Tribal methylmercury water quality criterion, NPDES permitting and TMDL development, and source management and control strategies. For example, the water quality standards portion of this policy would address issues such as how the water quality standards variance and use attainability analysis processes could be used to address legacy contaminants. Also, EPA expects that, as a result of this revised methylmercury water quality criterion, together with the more sensitive method for detecting mercury, there will be an increase in the number of waterbodies

reported on State 303(d) lists as impaired due to mercury contamination. Thus, the policy would also discuss approaches for managing the development of TMDLs for waterbodies impaired by mercury. This would include approaches for addressing waterbodies where much of the mercury is from atmospheric sources, and how TMDLs can take into account ongoing efforts to address sources of mercury, such as programs under the Clean Air Act and pollution prevention activities.

The policy would also address numerous issues associated with point source discharges of mercury such as determining the need for a WQBEL in NPDES permits and, where needed, developing and implementing those limits. EPA intends to take the following factors or assumptions into account when it addresses these issues: the unique properties of mercury; EPA's expectation that there will likely be a substantial increase in the number of point source discharges needing WQBELs as a result of the new more sensitive method; and, in most cases, the relatively small contribution from point source discharges to the total loadings of mercury to a waterbody.

Given the ongoing atmospheric sources of mercury and the long-term cycling of mercury in the environment, the most effective means of protecting public health for the next few decades will continue to be the issuance of fish consumption advisories by State and Tribal authorities, to ensure the public knows what level of fish consumption from specific waters is safe. EPA also emphasizes that the science underlying today's recommended section 304(a) water quality criterion is sound and recommends that States and authorized Tribes consider using an appropriate RSC in establishing and issuing fish consumption advisories as described in the fish advisory guidance (USEPA, 2000e). However, effective source control and management programs need to be initiated and developed in the coming few years to begin the long-term process of recovery from the widespread mercury contamination evident in our aquatic environments, with the goal of reducing mercury contamination so that fish consumption advisories can be removed.

EPA believes that flexibility may be appropriate as water quality standards based on today's methylmercury water quality criterion are implemented. Today's notice serves as an initiation of dialogue with stakeholders on recommended approaches for using today's section 304(a) water quality criterion guidance and managing mercury contamination in the aquatic environment. EPA is interested in obtaining information, views, suggestions, and innovative approaches from the public. EPA is particularly interested in specific examples or model approaches for management of mercury contamination at the Federal, State, Tribal, and local level. EPA anticipates this dialogue will be facilitated by a variety of means, which may include public meetings, meetings with stakeholders, and written correspondence and responses.

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Dated: December 21, 2000.

J. Charles Fox,

Assistant Administrator for Water.

[FR Doc. 01–217 Filed 1–5–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, 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 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning an information collection titled ''Occasional Qualitative Surveys.''

DATES: Comments must be submitted on or before March 9, 2001.

ADDRESSES: Interested parties are invited to submit written comments to Tamara R. Manly, Management Analyst (Regulatory Analysis), (202) 898–7453, Office of the Executive Secretary, Room F–4058, Attention: Comments/OES, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. All comments should refer to ''Occasional Qualitative Surveys.'' Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m. [FAX number (202) 898–3838; Internet address: *comments@ fdic.gov*]. Comments may also be submitted to the OMB desk officer for the FDIC: Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Tamara R. Manly, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

Title: Occasional Qualitative Surveys.

OMB Number: 3064–0127.

Frequency of Response: On occasion.

Affected Public: All financial institutions.

Estimated Number of Respondents: 5,000.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden: 5,000 hours.

General Description of Collection: The collection involves the occasional use of qualitative surveys to gather anecdotal information about regulatory burden, problems or successes in the bank supervisory process (including both safety-and-soundness and consumer-related exams), and similar concerns.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC'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; and (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.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record.

Dated at Washington, DC, this 2nd day of January, 2001.

Federal Deposit Insurance Corporation

Robert E. Feldman,

Executive Secretary.

[FR Doc. 01–437 Filed 1–5–01; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 1, 2001.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Midwest Community Bancshares, Inc., Marion, Illinois; to acquire 100 percent of the voting shares of The Egyptian State Bank, Carrier Mills, Illinois.

Board of Governors of the Federal Reserve System, January 2, 2001.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 01–398 Filed 1–5–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting; Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System

TIME AND DATE: 10 a.m., Wednesday, January 10, 2001.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 2lst Streets, NW., Washington, DC 20551

STATUS: Open

MATTERS TO BE CONSIDERED:

Discussion Agenda

1. Consideration of a final rule under Regulation Y (Bank Holding Companies and Change in Bank Control) to implement provisions of the Gramm-Leach-Bliley Act governing merchant banking investments made by financial holding companies (Docket No. R–1065). This rule revises and replaces an interim rule published for comment last year.

2. Any items carried forward from a previously announced meeting.

Note: This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $6 per cassette by calling 202–452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 for a recorded announcement of this meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement. (The Web site also includes procedural and other information about the open meeting.)

Dated: January 3, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01–501 Filed 1–4–01; 11:05 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting; Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: Approximately 10:30 a.m., Wednesday, January 10, 2001, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: January 3, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01–502 Filed 1–4–01; 11:01 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION/U.S. OFFICE OF PERSONNEL MANAGEMENT

Office of Communications

Cancellation of a Standard Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The U.S. Office of Personnel Management is cancelling the following Standard Form because of low usage: SF 144A, Statement of Prior Federal Service—Worksheet.

DATES: Effective January 8, 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: December 20, 2000.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 01–427 Filed 1–5–01; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

White House Commission on Complementary and Alternative Medicine Policy; Notice of Meeting

Notice is given of the third Town Hall Meeting of the White House Commission on Complementary and Alternative Medicine Policy. The purpose of the meeting is to convene the Commission for a public hearing to receive public testimony from individuals and organizations interested in the subject of federal policy regarding complementary and alternative medicine. Comments received at the meeting may be used by the Commission to prepare the report to the President as required by the Executive Order.

Comments should focus on the four areas that follow. Questions for consideration include, but are not limited to those presented below. For each question, please consider including in your response concerns, possible obstacles, existing programs, and suggested solutions to guide the Commission in their deliberations.

I. Coordinated Research and Development to Increase Knowledge of Complementary and Alternative Medicine Practices and Interventions

(A) What can be done to expand the current research environment so that practices and interventions that lie outside conventional science are adequately and appropriately addressed?

(B) What types of incentives are needed to stimulate the research of CAM practices and interventions by the public and private sectors?

(C) How can we more effectively integrate the CAM and conventional research communities to stimulate and coordinate research?

II. Guidance for Access to, Delivery of, and Reimbursement for Complementary and Alternative Medicine Practices and Interventions

(A) Do you have ready access to CAM practices and interventions?

(B) How can access to safe and effective CAM practices and interventions be improved?

(C) What types of CAM practices and interventions should be reimbursable through federal programs or other health care coverage systems?

III. Training, Education, Certification, Credentialing, Licensing, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine

(A) How can uniform standards of education, training, licensing and certification be applied to all CAM practitioners?

(B) What training and education should be required of all health care providers to assure access to safe and effective CAM practices and interventions?

(C) What sources of funds exist for the education and training of CAM practitioners?

(D) Are performance standards or practice guidelines needed to ensure the public will have access to the full range of safe and effective CAM practices and interventions?

IV. Delivery of Reliable and Useful Information on Complementary and Alternative Medicine to Health Care Professionals and the Public

(A) How can useful, reliable, and updated information about CAM practices and interventions be made more accessible? How would you like to receive such information?

(B) As a consumer, what kinds of information about CAM practices and interventions are most needed and important to you?

(C) As a health care provider, what kinds of information about CAM practices and interventions are most needed and important to you?

The Town Hall Meeting is open to the public and opportunities for oral comments and written statements by the public will be provided.

Name of Committee: The White House Commission on Complementary and Alternative Medicine Policy.

Date: January 23, 2001.

Time: 9 a.m.–9 p.m.

Place: Ames Auditorium, Lighthouse International Conference Center, 111 East 59th Street, New York, New York 10022–1201.

Contact Persons: Stephen C. Groft, Pharm. D., Executive Director, or Michele Chang, CMT, MPH, Executive Secretary, 6701 Rockledge Drive, Room 1010, MSC–7707, Bethesda, MD 20817–7707, Phone: (301) 435–7592 or 866–373–1124 (Toll-Free), Fax: (301) 480–1691, E-Mail: WHCCAMP@od.nih.gov.

The President established the White House Commission on Complementary and Alternative Medicine Policy on March 7, 2000 by Executive Order 13147. The mission of the White House Commission on Complementary and Alternative Medicine Policy is to provide a report, through the Secretary of the Department of Health and Human Services, on legislative and administrative recommendations for assuring that public policy maximizes the benefits of complementary and alternative medicine to Americans.

Because of the need to obtain the views of the public on these issues as soon as possible and because of the early deadline for the report required of the Commission, this notice is being provided at the earliest possible time.

Public Participation: The Town Hall meeting is open to the public with attendance limited by the availability of space on a first come, first serve basis. Members of the public who wish to present oral comment may register by calling 1–800–953–3298 or by accessing the website at *http://whccamp.hhs.gov* no later than January 16, 2001.

Oral comments will be limited to five minutes. Individuals who register to speak will be assigned in the order in which they registered. Due to time constraints, only one representative from each organization will be allotted time for oral testimony. The number of speakers and the time allotted may also be limited by the number of registrants. All requests to register should include the name, address, telephone number, and business or professional affiliation of the interested party, and should indicate the area of interest or question (as described above) to be addressed. Individuals interested in attending the meeting to observe the proceedings but not to provide oral testimony should also register.

Any person attending the meeting who has not registered to speak in advance of the meeting will be allowed to make a brief oral statement at the conclusion of the morning and afternoon sessions, if time permits, and at the chairperson's discretion.

Individuals unable to attend the meeting, or any interested parties, may send written comments by mail, fax, or electronically to the staff office of the Commission for inclusion in the public record. When mailing or faxing written comments, please provide, if possible, an electronic version or a diskette.

Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact the Commission staff at the address or telephone number listed no later than January 16, 2001.

Dated: December 28, 2000.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–409 Filed 1–5–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Request for Nominations of Candidates To Serve on the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee

The Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry are soliciting additional nominations for possible membership on the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee.

The Subcommittee is charged with providing advice and recommendations to the Director, CDC and Administrator, ATSDR, pertaining to CDC's and ATSDR's public health activities and research at respective DOE sites. Activities shall focus on providing the public and sovereign nations with a vehicle to express concerns and provide advice and recommendations to CDC and ATSDR. The Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee (INEELHES) was established to advise ATSDR and CDC on human health studies and public health activities that the agencies may undertake to address human exposures to historical releases of hazardous materials from the Idaho National Engineering and Environmental Laboratory.

CDC and ATSDR are seeking candidates with an interest in science, and a knowledge and understanding of community needs relative to environmental health. Close attention will be given to minority and female representation so long as the effectiveness of the Subcommittee is not impaired.

Nominations for new members will be accepted by fax or written correspondence. Information must include a description the qualifications of the nominee to serve, the assets the nominee would bring to the work of the Subcommittee and a current resume or curriculum vitae. The closing date for nominations is January 26, 2001. Nominations must be postmarked on or before the closing date.

Nominations should be sent to: Ms. Kitty Armstrong, Senior Committee Management Specialist, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, 1600 Clifton Road, NE., Mail Stop E–39, Atlanta, Georgia 30333. Nominations may be faxed to 404/639–2575.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both CDC and ATSDR.

Dated: January 2, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–422 Filed 1–5–01; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Request for Nominations of Candidates To Serve on the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Savannah River Site Health Effects Subcommittee

The Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry are soliciting additional nominations for possible membership on the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee.

The Subcommittee is charged with providing advice and recommendations to the Director, CDC and Administrator, ATSDR, pertaining to CDC's and ATSDR's public health activities and research at respective DOE sites. Activities shall focus on providing the public and sovereign nations with a vehicle to express concerns and provide advice and recommendations to CDC and ATSDR. The Savannah River Site Health Effects Subcommittee (SRSHES) was established to advise the ATSDR and CDC on human health studies and public health activities that the agencies may undertake to address human exposures to historical releases of hazardous materials from the Savannah River Site. CDC and ATSDR are seeking candidates with an interest in science, and a knowledge and understanding of community needs relative to environmental health. Close attention will be given to minority and female representation so long as the effectiveness of the Subcommittee is not impaired.

Nominations for new members will be accepted by fax or written correspondence. Information must include a description the qualifications of the nominee to serve, the assets the nominee would bring to the work of the Subcommittee and a current resume or curriculum vitae. The closing date for this round of nominations is January 26, 2001. Nominations must be postmarked on or before the closing date.

Nominations should be sent to: Ms. Kitty Armstrong, Senior Committee Management Specialist, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, 1600 Clifton Road, NE., Mail Stop E–39, Atlanta, Georgia 30333. Nominations may be faxed to 404/639–2575.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and ATSDR.

Dated: January 2, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–423 Filed 1–5–01; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

Name: Mine Safety and Health Research Advisory Committee (MSHRAC).

Time and Date: 9 a.m.–4 p.m., January 24, 2001.

Place: The Washington Court, 525 New Jersey Avenue, NW, Washington, DC 20001–1527.

Status: Open to the public, limited only by space available. The meeting

room accommodates approximately 50 people.

Purpose: The Committee is charged with advising the Secretary; the Director, Centers for Disease Control and Prevention (CDC); and the Director, National Institute for Occupational Safety and Health (NIOSH), CDC, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), Section 102(b)(2).

Matters to be Discussed: Agenda items include the Acting Director's comments; Report from Associate Director-Mining; Dust Monitoring Update; Ground Control Update; Self-contained Self-rescuer Initiative Update; NIOSH Activities as Related to Libby, MT, Asbestos Issue; and future activities of the Committee.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Lewis V. Wade, Ph.D., Executive Secretary, MSHRAC, NIOSH, CDC, 200 Independence Avenue, SW., Room 715–H Humphrey Building, Washington, DC 20201, telephone 202/401–2192, fax 202/260–4464.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 2, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–424 Filed 1–5–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 65 FR 70916, dated November 28, 2000) is amended to revise the mission statement for the Management Analysis and Services Office, Office of Program Services, to (1) reflect responsibility for coordinating CDC's special events activities and (2) realign internal subordinate functions.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete the functional statement for the *Management Analysis and Services Office (CA59), Office of Program Services (CA5),* and insert the following:

(1) Plans, coordinates, and provides CDC-wide administrative, technical, management, and information services in the following areas: policy development and consultation, studies and surveys, delegations of authorities, organizations and functions, information security, Privacy Act, confidentiality management, records management, printing procurement and reproduction, classroom and meeting management, forms design and management, publications distribution, mail services, public inquiries, reports and committee management, special events coordination; (2) develops and implements policies and procedures in these areas; (3) conducts management control reviews and coordinates IG/GAO audits; (4) maintains liaison with HHS, General Services Administration, the Government Printing Office, National Archives and Records Administration, and other Government and private agencies.

Delete the functional statement for the *Committee Management and Program Panels Activity (CA592)* and insert the following:

(1) Develops and manages, in conjunction with CDC's grants management requirements, a CDC-wide special emphasis panel that is the primary review mechanism for assuring scientific and programmatic review of applications for grant support; (2) coordinates committee management activities, including Federal advisory committees, for CDC; (3) plans and coordinates CDC special events.

Delete the functional statement for the *Management Procedures Branch (CA594)* and insert the following:

(1) Manages the CDC policy issuance system to include policy development, dissemination, and advisory services; interprets HHS and other directives and assesses their impact on CDC policy, and maintains the official CDC library of administrative management policy and procedures manuals; (2) directs the agency-wide confidentiality management function to process applications for approval to collect sensitive research data in accordance with special confidentiality authorities in Sections 301(d) and 308(d) of the Public Health Service Act; (3) coordinates IG/GAO audit activities; (4) provides consultation and assistance to CDC program officials and staff in complying with the requirements of the Privacy Act and accompanying guidelines and regulations; (5) provides forms management services, including development, coordination of clearances, and inventory management; (6) plans, develops, and implements policies and procedures in these areas, as appropriate.

Delete the functional statement for the *Management Analysis Branch (CA597)* and insert the following:

(1) Provides consultation and assistance to CDC program officials on the establishment, modification, or abolishment of organizational structures and functions; reviews and analyzes organizational changes; and develops documents for approval by appropriate CDC or HHS officials; (2) conducts management and operational studies for CDC to improve the effectiveness and efficiency of management and administrative systems techniques, policies, and organizational structures; (3) interprets, analyzes, and makes recommendations concerning delegations and redelegations of program and administrative authorities, and develops appropriate delegating documents; (4) develops and coordinates the implementation and conduct of CDC-wide information security programs; (5) conducts a CDC-wide records management program, including provision of technical assistance in the development and conduct of electronic records management activities; (6) plans, directs, and coordinates requirements of OMB Circulars A–76 and A–123 to conduct management review activities and to determine whether certain Agency functions might be more appropriately carried out through or by commercial sources; (7) plans, develops, and implements policies and procedures in these areas, as appropriate.

Delete the functional statement for the *Management Services Branch (CA598)* and insert the following:

(1) Plans and conducts a publications management program, including development, production, procurement, distribution, and storage of CDC publications; (2) plans, directs, coordinates, and implements CDC-wide information distribution services and mail and messenger services, including the establishment and maintenance of mailing lists; (3) maintains liaison with contract suppliers, HHS, the Government Printing Office, and other Government agencies on matters pertaining to printing, copy preparation,

reproduction, and procurement of printing; (4) serves as the focal point for recommending policies and establishing procedures for matters pertaining to energy conservation and recycling; (5) receives and reviews requests received from the public for information and publications, and responds to the requests or forwards to the appropriate CDC program for action; (6) manages the CDC learning environment through classroom and meeting support for CDC's Atlanta campuses; (7) plans, develops, and implements policies and procedures in these areas, as appropriate.

Dated: December 18, 2000.

Jeffrey P. Koplan,

Director.

[FR Doc. 01–462 Filed 1–5–01; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The National Epidemiologic Survey on Alcohol and Related Conditions

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 17, 2000, page 61342 and allowed 60-days for public comment. No public comments was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: The National Epidemiologic Survey on Alcohol and Related Conditions. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will determine the incidence and prevalence of alcohol use disorders in a representative sample of the United States population with the primary purpose of estimating the extent and distribution of alcohol consumption, alcohol use disorders and their associated psychological and medical disabilities across major sociodemographic subgroups. The primary objectives of this first wave of this longitudinal study is to understand the relationships between alcohol consumption, alcohol use disorders and their related disabilities with a view towards designing more effective treatment and intervention programs. The findings will provide valuable information concerning: (1) Trends in alcohol use disorders and their related disabilities in subgroups of the population of special concern; (2) identification of subgroups at high risk for alcohol use disorders that may be complicated by associated psychological and medical disabilities; (3) incidence of alcohol use disorders and their associated disabilities with a view toward understanding their natural history; (4) treatment utilization of alcohol use disorders in order to determine unmet treatment need and linguistic, social, economic and cultural barriers to treatment; (5) the college-aged segment of the population at high risk for binge drinking and its adverse consequences; and (6) the identification of safe and hazardous levels of drinking as they relate to the development of alcohol use disorders and their associated disabilities. *Frequency of Response:* On occasion. *Affected Public:* Individuals. *Type of Respondents:* Adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 48,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 1.00; and *Estimated Total Annual Burden Hours Requested:* 48,000. The annualized cost to respondents is estimated at: $576,000.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Bridget Grant, Chief, Biometry Branch, Division of Biometry and Epidemiology, NIAAA, NIH, Willco Building, Suite 514, 6000 Executive Boulevard, Bethesda, Maryland 20892–7003, or call non-toll-free number (301) 443–7370 or E-mail your request, including your address to: *Bgrant@willco.niaaa.nih.gov.*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before February 7, 2001.

Dated: November 22, 2000.

Stephen Long,

Executive Officer, NIAAA.

[FR Doc. 01–408 Filed 1–5–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Request to Amend Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt.

The following applicant requests a permit amendment to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*):

Applicant: Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, Hadley, Massachusetts

Permit No.: TE–697823

This applicant requests to amend their current permit for take activities for all listed species in the states of Connecticut, Delaware, Maine, Maryland, Massachusetts, New

Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia, and the District of Columbia for the purpose of scientific research and enhancement of survival of the species, to include the recently listed Gulf of Maine distinct population segment of Atlantic salmon (*Salmo salar*).

DATES: Written comments on this request for a permit amendment must be received on or before February 7, 2001.

ADDRESSES: Written data or comments should be submitted to the Regional Endangered Species Permits Coordinator, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035; facsimile: 413–253–8482.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with this request for an amendment are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 20 days of the date of publication of this notice to the address above; telephone: 413–253–8628.

Dated: December 19, 2000.

Dr. Mamie A. Parker,

Acting Regional Director.

[FR Doc. 01–403 Filed 1–5–01; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management; Alaska

[AK–921–1410–BK–P]

Notice for Publication; Filing of Plat of Survey; Alaska

The plat of survey of the following described land was officially filed in the Alaska State Office, Anchorage, Alaska, on the date indicated.

A plat representing the dependent resurvey of Tract A, U.S. Survey No. 465, Alaska, situated near the westerly shore of Shelikof Strait, in Alaska, was accepted November 1, 2000, and was officially filed November 8, 2000.

This plat was prepared at the request of the National Park Service to delineate the surrounding public lands.

This plat will immediately become the basic record for describing the land for all authorized purposes. This survey has been placed in the open files in the Alaska State Office and is available to the public as a matter of information.

All inquiries relating to these lands should be sent to the Alaska State Office, Bureau of Land Management, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599; 907–267–1403.

Daniel L. Johnson,

Chief, Branch of Field Surveys.

[FR Doc. 01–404 Filed 1–5–01; 8:45 am]

BILLING CODE 1410–BK–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service (MMS)

Outer Continental Shelf (OCS), Alaska Region, Beaufort Sea, Proposed Liberty Development and Production Plan (DPP)

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of Availability of the Draft Environmental Impact Statement (EIS) and Locations and Dates of Public Hearings for British Petroleum Exploration (Alaska) (BPXA) Inc.'s Proposed Liberty DPP Offshore Alaska.

SUMMARY: The MMS is issuing a draft EIS for the BPXA Inc.'s proposed Liberty Development Project DPP in the Beaufort Sea, Alaska. The U.S. Army Corps of Engineers (COE) and the Environmental Protection Agency (EPA) were cooperating agencies, with the MMS, in preparing the EIS. Information on the availability of the EIS and dates and locations for public hearings and submission of comments are presented in this notice.

FOR FURTHER INFORMATION CONTACT: For matters pertaining to this notice, contact Mr. Fred King (Alaska OCS Region, Anchorage) at (907) 271–6696 or toll free at 1–800–764–2627.

DATES: Comments on the draft EIS will be accepted until March 13, 2001.

SUPPLEMENTARY INFORMATION: The MMS, in cooperation with the COE and EPA, prepared a draft EIS on BPXA Inc.'s proposed Liberty Development Project DPP. This EIS additionally serves as the environmental analysis for the BPXA's Oil Discharge Prevention and Contingency Plan (ODPCP) and the construction and operation of a pipeline that would be associated with any Right-of-Way (ROW) for the OCS portion of the proposed Liberty pipeline. The public review for the DPP, ODPCP, and ROW will be announced separately by the MMS Alaska OCS Region.

This EIS is also intended to meet NEPA compliance and public notice requirements for EPA's issuance of a National Pollutant Discharge Elimination System (NPDES) permit, pursuant to Section 402 of the Clean Water Act. By this notice, the EPA is seeking public review and comment of the NPDES permit and explanatory fact sheet which are included as Appendix I in the draft EIS.

The Liberty prospect is located on the OCS in the Beaufort Sea northeast of the Prudhoe Bay oil field. The MMS is the lead agency which developed the EIS, in cooperation with the COE and the EPA, as required by the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4371 *et seq.*). In February 1998, BPXA submitted a DPP, subsequently revised in November 1998 (Revision 1) and July 2000 (Revision 2), describing how they proposed to produce, develop, and transport oil from the Liberty Prospect using a manmade gravel island constructed on the Federal OCS and located in 22 feet of water about 6.1 miles offshore in Foggy Island Bay and 1.5 miles west of the abandoned Tern Island. The Liberty Island facility would be a self-contained offshore drilling operation with processing facilities. Oil would be transported to shore in a common carrier pipeline which connects with the Trans-Alaska Pipeline System. A new gravel mine site and offshore and onshore ice roads are part of the proposed project. The MMS based the EIS analyses on estimates of the kinds and amounts of activity onshore and offshore that could result from transporting personnel and equipment offshore, constructing the self-contained manmade gravel island and structures, installing structures and equipment on the island, drilling wells, and constructing a common carrier oil pipeline buried in an undersea trench to an onshore landfall and then elevated onshore by vertical support members to a tie-in with the existing onshore Badami oil pipeline, then to the Trans-Alaska Pipeline System.

The EIS addresses a range of potentially applicable technologies and construction options. The EIS evaluates the BPXA Proposal, a No-Action alternative, and a variety of alternatives that were developed in light of the most significant issues raised from scoping. The alternatives examine three island locations and pipeline routes, four pipeline designs, two types of upper slope protection for the production island, two gravel mine sites, and two pipeline burial depths. The EIS also evaluates the effects of oil spill response activities described in the ODPCP.

EIS Availability: You may obtain single copies of the draft EIS, ''OCS EIS, MMS 2001–001'' (three volumes), from the MMS, Alaska OCS Region, Attention: Mr. Fred R. King, (MS 8303), 949 E. 36th Avenue, Room 308, Anchorage, Alaska 99508–4363, or by

calling 1–800–764–2627. The Executive Summary of this draft EIS is also available as a separate document: Executive Summary, MMS 2001–002. In addition, the complete EIS is available on CD-ROM (MMS 2001–001 CD) and on the Internet at (*http://www.mms.gov/alaska/cproject/liberty*).

You may look at copies of the draft EIS in the following libraries and offices in Alaska:

Alaska MMS Public Information Resource Center, 949 E. 36th Avenue, Anchorage; Alaska Resources Library and Information Services, U.S. Department of the Interior, 3150 C Street, Suite 100, Anchorage;
Alaska State Library, State Office Building, 333 Willoughby, Juneau; Army Corps of Engineers Library, U.S. Department of Defense, Elmendorf Air Force Base, Anchorage;
Fairbanks North Star Borough Public Library (Noel Wien Library), 1215 Cowles Street, Fairbanks;
Kaveolook School Library, Kaktovik;
Juneau Public Library, 292 Marine Way, Juneau;
North Slope Borough School District Library/Media Center, Barrow;
Northern Alaska Environmental Center Library, 218 Driveway, Fairbanks;
Nuiqsut Library, Nuiqsut;
Tuzzy Consortium Library, Barrow;
University of Alaska Anchorage, Consortium Library, 3211 Providence Drive, Anchorage;
University of Alaska Fairbanks, Elmer E. Rasmuson Library, 310 Tanana Drive, Fairbanks;
University of Alaska, Fairbanks Institute of Arctic Biology, 311 Irving Building, Fairbanks;
University of Alaska-Juneau Library, 11120 Glacier Highway, Juneau;
Valdez Consortium Library, 200 Fairbanks Street, Valdez;
Z. J. Loussac Library, 3600 Denali Street, Anchorage;
Alaska Eskimo Whaling Commission Office, Barrow;
Alaska Inter-Tribal Council, 431 West 7th Avenue, Suite 201, Anchorage;
Barrow City Office, Barrow;
North Slope Borough Office, Barrow;
Kaktovik City Office, Kaktovik;
Nuiqsut City Office, Nuiqsut.

Public Hearings: Five public hearings will be held to receive comments on the draft EIS. The hearings will provide us with additional information that will help in evaluating the potential effects of the proposed project. Hearings will be held in Anchorage, Barrow, Kaktovik, Nuiqsut, and Fairbanks on the following dates and times:

February 15, 2001, 12–3 p.m. and 7–9 p.m., Z. J. Loussac Library, Wilda; Marston Theatre , 3600 Denali Street, Anchorage;
February 19, 2001, 7:30–10 p.m., Inupiaq Heritage Center, Barrow;
February 20, 2001, 7–10 p.m., Kaktovik Community Center, Kaktovik;
February 21, 2001, 7–10 p.m., at Kisik Community Center, Nuiqsut;
February 22, 2001, 6–9 p.m., at the Alaskaland Exhibit Hall, 2600 Airport Way, Fairbanks.

An Inupiat translator will be available at the public hearings held in Barrow, Kaktovik, and Nuiqsut. Oral and written comments on the draft EIS will be addressed in the final EIS.

If you wish to testify at a hearing, you may register prior to the hearing to schedule a preferred time by contacting the Alaska OCS Region at the above address or Mr. Fred King at (907) 271–6696 or toll free 1–800–764–2627 not later than 3 days prior to the hearing date. Every effort will be made to accommodate individuals who have not pre-registered to testify. Time limitations may make it necessary to limit the length of oral statements to 10 minutes. You may supplement an oral statement with a more complete written statement and submit it to a hearing official at the hearing or by mail until March 13, 2001. Written statements submitted at a hearing will be considered part of the hearing record. If you are unable to attend the hearing, you may submit written statements at the address below.

We will accept comments on the draft EIS until March 13, 2001. Address your comments to the Regional Director, Alaska OCS Region, Minerals Management Service, 949 East 36th Avenue, Room 308, Anchorage, Alaska 99508–4363.

Dated: December 21, 2000.

Carolita U. Kallaur,

Associate Director for Offshore Minerals Management.

[FR Doc. 01–426 Filed 1–5–01; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection

AGENCY: Office of Surface Mining Reclamation and Enforcement Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection request for 30 CFR 816, Permanent Program Performance Standards—Surface Mining Activities, has been forwarded to the Office of Management and Budget (OMB) for review and approval. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collections but may respond after 30 days. Therefore, public comments should be submitted to OMB by February 7, 2001, in order to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request, explanatory information and related form, contact John A. Trelease at (202) 208–2783, or electronically to jtreleas@osmre.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted a request to OMB to renew its approval of the collection of information found at 30 CFR 816, Permanent Program Performance Standards—Surface Mining Activities. OSM is requesting a 3-year term of approval for this information collection activity.

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 collection of information is listed in 30 CFR 816, which is 1029–0047.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on October 17, 2000 (65 FR 61363). No comments were received. This notice provides the public with an additional 30 days in which to comment.

The following information is provided for the information collection: (1) Title of the information collection; (2) OMB control number; (3) summary of the information collection activity; and (4) frequency of collection, description of the respondents, estimated total annual responses, and the total annual reporting and recordkeeping burden for the collection of information. Where appropriate, OSM has revised burden estimates to reflect current reporting

levels and adjustments based on reestimates of the burden or number of respondents.

Title: Permanent Program Performance Standards—Surface Mining Activities, 30 CFR Part 816.

OMB Control Number: 1029–0047.

Summary: Section 525 of the Surface Mining Control and Reclamation Act of 1977 provides that permittees conducting surface coal mining operations shall meet all applicable performance standards of the Act. The information collected is used by the regulatory authority in monitoring and inspecting surface coal mining activities to ensure that they are conducted in compliance with the requirements of the Act.

Bureau Form Number: None.

Frequency of Collection: Once, on occasion, quarterly and annually.

Description of Respondents: Surface coal mining operators.

Total Annual Responses: 731,787.

Total Annual Burden Hours: 355,405.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the following address. Please refer to the appropriate OMB control number in all correspondence.

ADDRESSES: Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* Department of Interior Desk Officer, 725 17th Street, NW., Washington, DC 20503; and to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 210–SIB, Washington, DC 20240.

Dated: January 3, 2001.

Richard G. Bryson,

Chief, Division of Regulatory Support.

[FR Doc. 01–428 Filed 1–5–01; 8:45 am]

BILLING CODE 4310–05–M

UNITED STATES INTERNATIONAL TRADE COMMISSION

[USITC SE–01–001]

Notice of Sunshine Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: January 12, 2001 at 11 a.m.

PLACE: Room 101, 500 E Street S.W., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meeting: none.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 731–TA–624–625 (Review)(Helical Spring Lock Washers from China and Taiwan)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on January 25, 2001.)
5. Inv. Nos. 731–TA–470–472 (Review)(Silicon Metal from Argentina, Brazil, and China)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on January 25, 2001.)
6. Inv. Nos. 731–TA–671–673 (Review)(Silicomanganese from Brazil, China, and Ukraine)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on January 25, 2001.)
7. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: January 2, 2001.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–578 Filed 1–4–01; 2:26 pm]

BILLING CODE 7020–02–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–001]

NASA Advisory Council (NAC), Aero-Space Technology Advisory Committee, Goals Subcommittee; Meeting.

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Aero-Space Technology Advisory Committee, Goals Subcommittee.

DATES: Tuesday, February 6, 2001, 8:30 a.m. to 5 p.m.; Wednesday, February 7, 2001, 8:30 a.m. to 5 p.m.

ADDRESSES: National Aeronautics and Space Administration, Room 9H40, 300 E Street, SW, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Mary-Ellen McGrath, Office of Aerospace Technology, National Aeronautics and Space Administration, Washington, DC 20546 (202/358–4729).

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

Tuesday, February 6, 2001

—Aviation Noise Reduction Overview
—Noise Reduction Strategic Thrust Weights
—Noise Reduction Technologies Briefing
—NASA Progress Toward Noise Reduction Targets
—Noise Reduction Assessment, Priorities, and Directions
—Subcommittee Caucus

Wednesday, February 7, 2001

—Aviation Safety Overview
—Aviation Safety Strategic Thrust Weights
—Aviation Safety Technologies Briefing
—NASA Progress Toward Safety Targets
—Overall Safety Assessment, Priorities, and Directions
—Analysis Issues and Developments
—Subcommittee Caucus

In addition, for those interested, there will be an Integrated Space Transportation Plan (ISTP) presentation from 9 a.m.–11 a.m., February 8, 2001. The presentation will provide updated program long-term goals and directions. It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Beth M. McCormick,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 01–432 Filed 1–5–01; 8:45 am]

BILLING CODE 7510–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for OMB Review; Request for Review of an Expiring Information Collection: OPM Form 805 Series

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, May 22, 1995), this notice announces that the Office of Personnel Management has submitted simultaneously with publication of this notice a request to the Office of Management and Budget for review of an expiring information collection: OPM

Form 805 Series. OPM Form 805, Application to be Listed Under the Voting Rights Act of 1965, is used to elicit information from persons applying for voter registration under the authority of the Voting Rights Act of 1965. The requirements for voter eligibility vary from State to State; therefore, OPM Form 805 is a blanket number covering a number of forms that conform to the individual State's requirements. For a number of years, there were forms for 10 States: Alabama, Arizona, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, South Carolina, Texas (English and Spanish language versions), and Utah. Because OPM has never been asked to list voters in Arizona, New Mexico, North Carolina, and Utah, we allowed the approval of those forms to lapse in 1997 at the request of the Voting Rights Section in the Civil Rights Division of the Department of Justice. The form requires 20 minutes to complete. Approximately 10 individuals complete the form annually for a total public burden of 4 hours.

For copies of this proposal, call Ms. Mary Beth Smith-Toomey on (202) 606–8358 or email mbtoomey@opm.gov.

DATES: Comments on this proposal should be received on or before February 7, 2001.

ADDRESSES: Send or deliver comments to—

Anna Marie Schuh, Assistant Director for Merit Systems Oversight, Office of Personnel Management, 1900 E Street, NW., Room 7677, Washington, DC 20415–6000

and

Joseph Lackey, OPM Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW., Room 10235, Washington, DC 20503

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION, CONTACT: P. Kaziah Clayton, Office of Merit Systems, Oversight and Effectiveness, (202) 606–2531, pkclayto@opm.gov.

U.S. Office of Personnel Management.

Janice R. Lachance,

Director.

[FR Doc. 01–429 Filed 1–5–01; 8:45 am]

BILLING CODE 6325–01–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) *Collection title:* Railroad Unemployment Insurance Act Applications.

(2) *Form(s) submitted:* SI–1a, SI–1b, SI–3, SI–7, SI–8, ID–7H, ID–11A, ID–11B.

(3) *OMB Number:* 3220–0039.

(4) *Expiration date of current OMB clearance:* 4/30/2001.

(5) *Type of request:* Revision of a currently approved collection.

(6) *Respondents:* Individuals or Households, Business or other for-profit.

(7) *Estimated annual number of respondents:* 55,400.

(8) *Total annual responses:* 271,900.

(9) *Total annual reporting hours:* 27,971.

(10) *Collection description:* Under Section 2 of the Railroad Unemployment Insurance Act, unemployment and sickness benefits are provided for qualified railroad employees. The collection obtains information needed to determine eligibility for an amount of such benefits from railroad employees and physicians. Also collects information from individuals acting on behalf of sick or injured employees and supplemental information from railroad employers regarding settlement of injuries or accidents for which sickness benefits were paid.

Additional Information or Comments

Copies of the forms and supporting documents can be obtained from Chuck Mierzwa, the agency clearance officer (312–751–3363). Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois, 60611–2092 and the OMB reviewer, Joe Lackey (202–395–7316), Office of Management and Budget, Room 10230, New Executive Office Building, Washington, DC 20503.

Chuck Mierzwa,

Clearance Officer.

[FR Doc. 01–405 Filed 1–5–01; 8:45 am]

BILLING CODE 7905–01–M

DEPARTMENT OF STATE

[Public Notice 3534]

Culturally Significant Objects Imported for Exhibition Determinations: ''Van Gogh Portraits: Face to Face''

AGENCY: United States Department of State.

ACTION: Amendment.

SUMMARY: On February 16, 2000, Notice was published on page 7902 of the **Federal Register** (Volume 65, Number 32) by the Department of State pursuant to Public Notice 3228 relating to the exhibit ''Van Gogh Portraits: Face to Face.'' The referenced Notice is hereby amended to add a venue. After ''January 14, 2001 and before ''is in the national interest,'' insert the following additional language: ''and at the Museum of Modern Art, New York, NY from January 30, 2001, through May 15, 2001.''

FOR FURTHER INFORMATION CONTACT: For further information, including a list of exhibit objects, contact Jacqueline Caldwell, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202/619–6982). The address is U.S. Department of State, SA–44; 301 4th Street, S.W., Room 700, Washington, D.C. 20547–0001.

Dated: December 28, 2000.

William B. Bader,

Assistant Secretary for Educational and Cultural Affairs, United States Department of State.

[FR Doc. 01–458 Filed 1–5–01; 8:45 am]

BILLING CODE 4710–08–P

TENNESSEE VALLEY AUTHORITY

Meeting of the Regional Resource Stewardship Council

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Notice of meeting.

SUMMARY: The Regional Resource Stewardship Council (Regional Council) will hold a meeting to consider various matters. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2, (FACA).

The meeting agenda includes the following/briefings:

1. Instream flows and recreation.
2. Tax exempt payments.
3. Recommendation from the Water Quality Subcommittee on aquatic plant management.
4. Public comments.
5. Subcommittee reports.
6. Water quality issues below tributary reservoirs.

It is the Regional Council's practice to provide an opportunity for members of the public to make oral public comments at its meetings. Public comment session is scheduled from 11:00 a.m.–noon CST. Members of the public who wish to make oral public comments may do so during the Public comments portion of the agenda. Up to one hour will be allotted for the Public comments with participation available on a first-come, first-served basis. Speakers addressing the Council are requested to limit their remarks to no more than 5 minutes. Persons wishing to speak register at the door and are then called on by the Council Chair during the public comment period. Hand-out materials should be limited to one printed page. Written comments are also invited and may be mailed to the Regional Resource Stewardship Council, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 11A, Knoxville, Tennessee 37902.

DATE: The meeting will be held on Thursday, January 18, 2001, from 8:30 a.m. to 5 p.m. CST.

ADDRESS: The meeting will be held in Nashville, Tennessee, at the Sheraton Downtown Hotel, 623 Union Street, Nashville, Tennessee 37219, and will be open to the public. Anyone needing special access or accommodations should let the contact below know at least a week in advance.

FOR FURTHER INFORMATION CONTACT: Sandra L Hill, 400 West Summit Hill Drive, WT 11A, Knoxville, Tennessee 37902, (865) 632–2333.

Dated: December 19, 2000.

Kathryn J. Jackson,

Executive Vice President, River System Operations & Environment, Tennessee Valley Authority.

[FR Doc. 01–425 Filed 1–5–01; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Mercer and Middlesex Counties, New Jersey

AGENCY: Federal Highway Administration (FHWA), USDOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for changes being considered to Route 1 and intersecting roadways in the greater Penn's Neck Area to improve transportation service.

FOR FURTHER INFORMATION CONTACT: Robin Schroeder, Program Operations Director or Amy Fox, Environmental Coordinator, Federal Highway Administration, 840 Bear Tavern Road, Suite 310, West Trenton, NJ 08628.

SUPPLEMENTARY INFORMATION: Pursuant to Title 23, Code of Federal Regulations, Part 771, Environmental Impact and Related Procedures, the FHWA, in cooperation with the New Jersey Department of Transportation (NJDOT), will prepare an environmental impact statement in accordance with the National Environmental Policy Act (NEPA), on alternatives for modifications to Route 1 and intersecting roadways in the Penn's Neck Area, to improve transportation service. Generally, the section of Route 1 under evaluation extends from Alexander Road Interchange in West Windsor Township in Mercer County to Scudders Mill Road Interchange in Middlesex County. The EIS will evaluate the No-Action and Build Alternatives to determine potential impacts and costs associated with each.

An Environmental Assessment (EA)/ Section 4(F) Evaluation of some alternative solutions for mobility and congestion problems in the Penn's Neck area of Route 1 was developed by FHWA and NJDOT and made available to the public and review agencies during October 2000. Subsequently, a decision was made by Governor Christine Todd Whitman to prepare an EIS to allow broader public participation in the process and a fuller evaluation of alternatives and impacts. After publication of this Notice, the FHWA in cooperation with NJDOT will continue the scoping process begun during the preparation of the EA to evaluate alternatives already under review and to identify additional possible alternatives. This process will also identify significant issues to be addressed in the EIS.

To ensure that issues involving this proposed action are addressed fully and significant concerns are identified, written comments, suggestions or questions should be directed to the FHWA at the address provided above or directed to: Mr. Andras Fekete, Manager, Bureau of Environmental Services, New Jersey Department of Transportation, 1035 Parkway Avenue, Trenton, NJ 08625–0600, Telephone: 609–530–2824.

The public will receive notices on location and time of future opportunities for participation at meetings and public hearings through newspaper advertisements and other means. If you wish to be placed on the mailing list to receive further information as the project develops, contact Mr. Andras Fekete at the address above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation of Federal programs and activities apply to this program)

Issued on: December 28, 2000.

Robin Schroeder,

Program Operations Director, FHWA—New Jersey Division, Trenton.

[FR Doc. 01–406 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket Number NHTSA–2000–8273]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comment on proposed collections of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes two collections of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 9, 2001.

ADDRESSES: Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted to U.S. Department of Transportation Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB Control Number. It is requested, but not required, that one original plus two copies of the comments be provided. The Docket Section is open on weekdays from 10:00 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for

collection of information may be obtained at no charge from Ms. Henrietta L. Spinner, NHTSA, 400 Seventh Street, Southwest, Room 5320, NPS–32, Washington, DC 20590. Ms. Spinner's telephone number is (202) 366–0846. Please identify the relevant collection of information by referring to its OMB clearance number.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8 (d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including 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.

In compliance with these requirements, NHTSA asks for public comment on the following current collections of information for which the agency is seeking extension of their approval from OMB:

Title: 49 CFR 537—Automotive Fuel Economy Reports.

OMB Control No.: 2127–0019.

Form Number: This collection of information uses no standard form.

Abstract: Part 537 requires automobile manufacturers to submit semi-annual reports to NHTSA regarding their efforts to improve fuel economy.

Type of Request: Extension of a currently approved collection.

Affect Public: Business or other for-profit organizations.

Requested Expiration Date: Three years from approval date.

Summary of the Collection of Information: NHTSA ensures that automobile manufacturers comply with 49 CFR part 537—Automotive Fuel Economy Reports. Part 537 requires that automobile manufacturers submit reports to NHTSA regarding their efforts to improve automotive fuel economy.

Section 32907 of Chapter 329 of title 49 of the United States Code requires each automobile manufacturer (other than those low volume manufacturers which were granted an alternative fuel economy standard under section 32902 (d)) to submit semi-annual reports to the agency relating to that manufacturers' efforts to comply with average fuel economy standards. One report is due during the 30-day period preceding the beginning of each model year (the ''pre-model year report'') and the other is due during the 30-day period beginning on the 180th day of the model year (the ''mid-model year report'').

Section 32907 (a)(1) of Chapter 329 provides that each report must contain a statement as to whether the manufacturer will comply with average fuel economy standards for that year, a plan describing the steps the manufacturer took or will take to comply with the standards, and any other information the agency may require. Whenever a manufacturer determines that a plan it has submitted in one of its reports is no longer adequate to assure compliance, it must submit a revised plan.

Description of the Need for the Information and Proposed Use of the Information: This information assists NHTSA in evaluating automobile manufacturers' plans for complying with average fuel economy standards and in preparing an annual review of the average fuel economy standards. The information is collected by NHTSA by having the automobile manufacturers mail their semi-annual automotive fuel economy reports and/or submit a copy on computer diskette to the agency. The required information is used for four basic purposes. These purposes are: (a) To give NHTSA advance indication if any manufacturer will fail to comply with the applicable average fuel economy standards; (b) to give NHTSA necessary information to prepare fuel economy reports; (c) to assist NHTSA in responding to general information requests concerning automotive fuel economy, which are routinely received from Congress, other parts of the Executive branch, and the public; and (d) to provide NHTSA with detailed and accurate technical and economic information used to evaluate possible future average fuel economy standards which may be established by NHTSA.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information): NHTSA anticipates that no more than 17 vehicle manufacturers will be affected by the reporting requirements. NHTSA does not believe any of these 17 manufacturers are a small business (*i.e.,* one that employs less than 500 persons). NHTSA anticipates a total of about 40 responses may be filed by these 17 manufacturers. Most manufacturers will respond semiannually; however, a few manufacturers may respond more frequently.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information: NHTSA estimates that the vehicle manufacturers will incur a total annual reporting and cost burden of 3,300 hours and $645,000.

Title: 49 CFR 583—Automobile Parts Content Labeling.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2127–0573.

Form Number: This collection of information uses no standard form.

Requested Expiration Date of Approval: Three years from approval date.

Summary of the Collection of Information: NHTSA ensures that automobile manufacturers comply with 49 CFR Part 583—Automobile Parts Content Labeling. Part 583 establishes requirements for the disclosure of information relating to the countries of origin of the equipment of new passenger motor vehicles.

Description of the Need for the Information and Proposed Use of the Information: This information will be used by NHTSA to determine whether manufacturers are complying with the American Automobile Labeling Act (49 United States Code 32304). The American Automobile Labeling Act requires all new passenger motor vehicles (including passenger cars, certain small buses, all light trucks and multipurpose passenger vehicles with a gross vehicle weight rating of 8,500 pounds or less), to bear labels providing information about domestic and foreign content of their equipment. With the affixed label on the new passenger motor vehicle, it serves as an aid to potential purchasers in the selection of new passenger motor vehicles by providing them with information about the value of the U.S./Canadian and foreign parts of each vehicle, the countries of origin of the engine and transmission, and the site of the vehicle's final assembly.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the

Collection of Information): NHTSA anticipates that no more than 17 vehicle manufacturers will be affected by these reporting requirements. NHTSA does not believe any of these 17 manufacturers are a small business (*i.e.,* one that employs less than 500 persons). Manufacturers of new passenger motor vehicles, including passenger cars, certain small buses, and light trucks with a gross vehicle weight rating of 8,500 pounds or less, must file a report annually.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information: NHTSA estimates that the vehicle manufacturers will incur a total annual reporting and cost burden of 6,066 hours and $4,700,000. The amount includes annual burden hours incurred by multi-stage manufacturers and motor vehicle equipment suppliers.

Issued on: January 2, 2001.

Noble N. Bowie,

Acting Associate Administrator for Safety, Performance Standards.

[FR Doc. 01–433 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33979]

CenTra, Inc., et al.—Continuance in Control Exemption—Riverview Trenton Railroad Company

CenTra, Inc. (CenTra) and Crown Enterprises, Inc. (Crown) (collectively applicants), noncarriers, have filed a verified notice of exemption to continue in control of the Riverview Trenton Railroad Company (Riverview), upon Riverview's becoming a Class III railroad.

The transaction was expected to be consummated on the effective date of the exemption. The earliest the transaction could be consummated was December 20, 2000, 7 days after the exemption was filed.

This transaction is related to STB Finance Docket No. 33980, *Riverview Trenton Railroad Company—Acquisition and Operation Exemption—Crown Enterprises, Inc.,* wherein Riverview seeks to acquire a line of railroad approximately 1.5 miles long in Riverview and Trenton, MI.

CenTra controls Crown and Crown controls Jefferson Terminal Railroad Company (Jefferson), an entity formed to become a Class III railroad, which has filed a notice of exemption to acquire and operate a lined owned by Crown in Detroit, MI.[1]

Applicants state that (i) the rail lines of Riverview and Jefferson will not connect with each other, (ii) the transaction is not part of a series of transactions that would connect the railroads with each other and there is no other railroad in the corporate family, and (iii) the transaction does not involve a Class I carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

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. 33979, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Daniel C. Sullivan, Esq., Sullivan & Hincks, 122 W. 22nd Street, Suite 350, Oak Brook, IL 60523.

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

Decided: December 29, 2000.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 01–329 Filed 1–8–01; 8:45 am]

BILLING CODE 4915–00–P

[1] The notice of exemption was filed in *Jefferson Terminal Railroad Co.—Acquisition and Operation Exemption—Crown Enterprises, Inc.,* STB Finance Docket No. 33950 (STB served and published at 65 FR 66802 on Nov. 7, 2000). A petition filed by the City of Detroit to revoke the exemption is currently pending.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33980]

Riverview Trenton Railroad Company—Acquisition and Operation Exemption—Crown Enterprises, Inc.

Riverview Trenton Railroad Company (Riverview), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from Crown Enterprises, Inc. and operate approximately 1.5 miles of rail line within a 76-acre parcel in Riverview and Trenton, MI.[1] The line connects with the track of the Canadian National Railway Company subsidiary Grand Trunk Western Railroad, Inc. (CN), over which Consolidated Rail Corporation (Conrail) has operated, at the exit from the southwesterly edge of the 195.45-acre DSC site, as the track traverses diagonally across the intersection of King Road and W. Jefferson Avenue, in Trenton, near the FN Tower and CN River Subdivision milepost 10.96. The line also connects with the track of the CN as the line exits the 76-acre parcel at the northwest corner where it traverses W. Jefferson Avenue near its junction with Ford Avenue in Riverview and extends into the so-called CN Penn Salt Yard, over which Conrail has operated, near CN River Subdivision milepost 9.39.[2]

This transaction is related to STB Finance Docket No. 33979, *CenTra, Inc., et al.—Continuance in Control Exemption—Riverview Trenton Railroad Company,* wherein CenTra, Inc., *et al.* has filed a verified notice to continue in control of Riverview upon its becoming a Class III rail carrier.

The transaction was expected to be consummated immediately after the effective date of the exemption. The earliest the transaction could be consummated was December 20, 2000, 7 days after the exemption was filed.[3]

[1] In addition, Riverview has acquired from DSC Ltd. (DSC), a noncarrier and nonaffiliate, related track and trackage rights within a 195.45-acre industrial site located adjacent to Riverview's 76-acre parcel.

[2] Riverview reports that all operations will occur within the Conrail Detroit Shared Asset Area as designated in a transaction approved by the Board, and consummated by the parties on June 1, 1999. *See CSX Corporation and CSX Transportation, Inc., Norfolk Southern Corporation and Norfolk Southern Railway Company—Control and Operating Leases/Agreements—Conrail Inc. and Consolidated Rail Corporation,* STB Finance Docket No. 33388, Decision No. 89 (STB served July 23, 1998).

[3] Riverview notes that it will apply to CN and Conrail for switching and interchanging of traffic to and from the tracks it owns, and/or will operate

Continued

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to reopen the proceeding 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. 33980, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Daniel C. Sullivan, Esq., Sullivan & Hincks, 122 W. 22nd Street, Suite 350, Oak Brook, IL 60523.

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

Decided: December 29, 2000.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams

Secretary.

[FR Doc. 01–330 Filed 1–5–01; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33985]

LB Railco, Inc.—Lease and Operation Exemption—San Francisco Port Commission

LB Railco, Inc. (LB Railco) has filed a verified notice of exemption under 49 CFR 1150.31 to operate lines leased from the San Francisco Port Commission between a junction with Union Pacific Services, near Amador Street and Cargo Way, and the Intermodal Container Transfer Facility, and thence beyond to Piers 92, 94, and 96, a total distance of approximately one-half mile in San Francisco, CA.

LB Railco indicates that it intends to commence operations by December 30, 2000. The earliest the transaction can be consummated is December 29, 2000 (7 days after the exemption was filed).

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to reopen the proceeding 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. 33985, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on John F. McHugh, McHugh & Barnes, P.C., 20 Exchange Place, New York, NY 10005.

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

Decided: December 29, 2000.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 01–331 Filed 1–5–01; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–577X]

Mohall Railroad, Inc.—Abandonment Exemption—in Bottineau, Renville, Ward and McHenry Counties, ND

On December 19, 2000, Mohall Railroad, Inc. (MRI) filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon a line of railroad known as the Mohall Line, extending from milepost 5.25 to milepost 35.0, a distance of 29.75 miles in Bottineau, Renville, Ward and McHenry Counties ND.[1] The line traverses U.S. Postal Service Zip Codes 58731, 58740, 58741, and 58750, and includes the stations of Deering (milepost 12.9), Wolseth (approximately milepost 18), and Glenburn (milepost 24.3).

The line does not contain federally granted rights-of-way. Any documentation in MRI's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by April 6, 2001.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each offer must be accompanied by a $1,000 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than January 29, 2001. Each trail use request must be accompanied by a $150 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–577X and must be sent to: (1) Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001; and (2) Mark S. Radke and Byron D. Olsen, Felhaber, Larson, Fenlon & Vogt, P.A., 601 Second Ave., South, Suite 4200, Minneapolis, MN 55402. Replies to the petition are due on or before January 29, 2001.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1545. [TDD for the hearing impaired is available at 1–800–877–8339.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

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under a trackage and right-of-way agreement to furnish cars, containers and trailers for the movement of traffic of Riverview and to provide service to move the resulting traffic generated by the proposed operation focusing upon intermodal shipments, but that it will not enter or operate any track or right-of-way of CN or Conrail.

[1] The Burlington Northern and Santa Fe Railway Company (BNSF), as successor to the Burlington Northern Railroad Company, is generally prohibited from abandoning in excess of 350 miles of rail lines in North Dakota, a mileage total BNSF has already reached. *See* section 402 of the Department of Transportation and Related Agencies Appropriation Act of 1982 (Pub. L. No. 97–102, 1982). This limitation applies to the abandonment of any BNSF lines in North Dakota, even after their sale to third parties, and would thus normally be applicable to the Mohall Line. However, by an amendment effective October 5, 2000, the specific segment of track involved here may be abandoned without being counted against this 350-mile limitation. *See* Pub. L. No. 106–940, sec. 372.

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

Decided: January 3, 2001.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 01–503 Filed 1–5–01; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 28, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 7, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–0016.

Form Number: IRS Form 706-A.

Type of Review: Extension.

Title: United States Additional Estate Tax Return.

Description: Form 706–A is used by individuals to compute and pay the additional estate taxes due under Code section 2032A(c). IRS uses the information to determine that the taxes have been properly computed. The form is also used for the basis election of section 1016(c)(1).

Respondents: Individuals or households.

Estimated Number of Respondents/Recordkeepers: 180.

ESTIMATED BURDEN HOURS PER RESPONDENT/RECORDKEEPER

Recordkeeping	3 hr., 17 min.
Learning about the law or the form.	2 hr., 11 min.
Preparing the form	1 hr., 40 min.
Copying, assembling, and sending the form to the IRS.	1 hr., 3 min.

Estimated Total Reporting/Recordkeeping Burden: 1,474 hours.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW, Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 01–444 Filed 1–5–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

January 2, 2001.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 7, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1573.

Regulation Project Number: REG–130477–00 and REG–130481–00 NPRM (formerly REG–209463–82 NPRM).

Type of Review: Extension.

Title: Required Distributions from Retirement Plans.

Description: The regulation permits a taxpayer to name a trust as the beneficiary of the employee's benefit under a retirement plan and use the life expectancies of the beneficiaries of the trust to determine the required minimum distribution, if certain conditions are satisfied.

Respondents: Individuals or households.

Estimated Number of Respondents: 1,000.

Estimated Burden Hours Per Respondent: 20 minutes.

Estimated Total Reporting/Recordkeeping Burden: 333 hours.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 01–445 Filed 1–5–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Proposed Agency Information Collection Activities; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Today, the Office of Thrift Supervision within the Department of the Treasury solicits comments on the Lending and Investment Package.

DATES: Submit written comments on or before March 9, 2001.

ADDRESSES:

Mail: Send comments to Manager, Dissemination Branch, Information Management and Services Division, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention 1550–0078.

Delivery: Hand deliver comments to the Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9:00 a.m. to 4:00 p.m. on business days, Attention 1550–0078.

Facsimiles: Send facsimile transmissions to FAX Number (202) 906–7755, Attention 1550–0078; or (202) 906–6956 (if comments are over 25 pages).

E–Mail: Send e-mails to ''public.info@ots.treas.gov'', Attention 1550–0078, and include your name and telephone number.

Public Inspection: Interested persons may inspect comments at the Public Reference Room, 1700 G St. NW., from 10:00 a.m. until 4:00 p.m. on Tuesdays and Thursdays or obtain comments and/or an index of comments by facsimile by telephoning the Public Reference Room at (202) 906–5900 from 9:00 a.m. until 5:00 p.m. on business days. Comments and the related index will also be posted

on the OTS Internet Site at ''www.OTS.treas.gov''.

FOR FURTHER INFORMATION CONTACT: William Magrini, Supervision, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, (202) 906–5744.

SUPPLEMENTARY INFORMATION:

Title: Lending and Investment.

OMB Number: 1550–0078.

Form Number: Not applicable.

Abstract: OTS amended 12 CFR 560.210 to conform to parallel provisions of the Board of Governors of the Federal Reserve System's Regulation Z, Truth-in-Lending. Savings associations are permitted to provide either a statement that periodic rates may substantially increase or decrease (together with the maximum interest rate and payment amount based on a $10,000 loan amount) or a fifteen-year historical example of interest rates and payments based on a $10,000 loan amount.

Current Actions: OTS proposes to renew this information collection without revision.

Type of Review: Renewal.

Affected Public: Business or For Profit.

Estimated Number of Respondents: 1082.

Estimated Time Per Respondent: 0.11 hours.

Estimated Total Annual Burden Hours: 436,428 hours.

Request for Comments: The OTS will summarize comments submitted in response to this notice or will include these comments in its request for OMB approval. All comments will become a matter of public record. The OTS invites comment on: (a) Whether the 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 collection of information; (c) ways to enhance the quality; (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or starting costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 3, 2001.

John E. Werner,

Director, Information & Management Services Division.

[FR Doc. 01–451 Filed 1–5–01; 8:45 am]

BILLING CODE 6720–01–P

Corrections

Federal Register
Vol. 66, No. 5
Monday, January 8, 2001

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 001213348–0366–02; I.D. 121100A]

RIN 0648–AO44

Fisheries of the Exclusive Economic Zone Off Alaska; Removal of Groundfish Closure

Correction

In rule document 00–33162 beginning on page 82298 in the issue of Thursday, December 28, 2000, make the following correction:

§679.22 [Corrected]

On page 82299, in the third column, in §679.22(l), paragraph designation ''(k)'' should read ''(l)''.

[FR Doc. C0–33162 Filed 1–5–01; 8:45 am]

BILLING CODE 1505–01–D

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

RIN 3038-AB56

Investment of Customer Funding

Correction

In rule document 00–32976 beginning on page 82270 in the issue of Thursday, December 28, 2000, make the following correction:

On page 82271, in the second column, in the first full paragraph, ten lines from the bottom, ''permit'' should read ''permittted''.

[FR Doc. C0–32976 Filed 1–5–01; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–310–1310–PB–01–24 1A]

Extension of Approved Information Collection, OMB Approval Number 1004–0160

Correction

In notice document 00–32655 beginning on page 80904 in the issue of Friday, December 22, 2000, the docket number and OMB approval number are corrected to read as set forth above.

[FR Doc. C0–32655 Filed 1–5–01; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

RIN 1215–AB09

Labor Condition Applications and Requirements for Employers Using Nonimmigrants on H–1B Visas in Specialty Occupations and as Fashion Models; Labor Certification Process for Permanent Employment of Aliens in the United States

Correction

In rule document 00–32088 beginning on page 80110 in the issue of Wednesday, December 20, 2000, make the following correction:

§655.736 [Corrected]

On page 80224, in the second column, in §655.736(b)(2)(iii), the second paragraph designation ''(ii)'' should read ''(iii)''.

[FR Doc. C0–32088 Filed 1–5–01; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Monday,
January 8, 2001

Part II

Department of the Treasury

Internal Revenue Service

26 CFR Part 54

Department of Labor

Pension and Welfare Benefits Administration

29 CFR Part 2590

Department of Health and Human Services

Health Care Financing Administration

45 CFR Part 146

Nondiscrimination in Health Coverage in the Group Market; Interim Final Rules and Proposed Rules

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 8931]

RIN 1545–AW02

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2590

RIN 1210–AA77

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

45 CFR Part 146

RIN 0938–AI08

Interim Final Rules for Nondiscrimination in Health Coverage in the Group Market

AGENCIES: Internal Revenue Service, Department of the Treasury; Pension and Welfare Benefits Administration, Department of Labor; Health Care Financing Administration, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final rules governing the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan. The rules contained in this document implement changes made to the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974 (ERISA), and the Public Health Service Act (PHS Act) enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

DATES: *Effective date.* The interim final rules are effective March 9, 2001.

Applicability dates. For rules describing when this section applies to group health plans and group health insurance issuers, see paragraph (i) of these interim regulations.[1]

Comment date. Written comments on these interim regulations are invited and must be received by the Departments on or before April 9, 2001.

ADDRESSES: Written comments should be submitted with a signed original and three copies (except for electronic submissions to the Internal Revenue Service (IRS) or Department of Labor) to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments.

Comments to the IRS can be addressed to: CC:M&SP:RU (REG–109707–97), Room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044.

In the alternative, comments may be hand-delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–109707–97), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224.

Alternatively, comments may be transmitted electronically via the IRS Internet site at: *http://www.irs.gov/tax regs/regslist.html.*

Comments to the Department of Labor can be addressed to: U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue NW., Room C–5331, Washington, DC 20210, *Attention:* Nondiscrimination Comments.

Alternatively, comments may be hand-delivered between the hours of 9 a.m. and 5 p.m. to the same address. Comments may also be transmitted by e-mail to: HIPAA702@pwba.dol.gov.

Comments to HHS can be addressed to: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2022–IFC, P.O. Box 26688, Baltimore, MD 21207.

In the alternative, comments may be hand-delivered between the hours of 8:30 a.m. and 5 p.m. to either: Room 443–G, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201 or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

All submissions to the Department of Labor will be open to public inspection and copying in the Public Documents Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue, NW., Washington, DC from 8:30 a.m. to 5:30 p.m.

All submissions to HHS will be open to public inspection and copying in room 309–G of the Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC from 8:30 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Amy J. Turner, Pension and Welfare Benefits Administration, Department of Labor, at (202) 219–7006; or Ruth A. Bradford, Health Care Financing Administration, Department of Health and Human Services, at (410) 786–1565.

SUPPLEMENTARY INFORMATION:

Customer Service Information:

Individuals interested in obtaining additional information on HIPAA's nondiscrimination rules may request a copy of the Department of Labor's booklet entitled ''Questions and Answers: Recent Changes in Health Care Law'' by calling the PWBA Toll-Free Publication Hotline at 1–800–998–7542 or may request a copy of the Health Care Financing Administration's new publication entitled ''Protecting Your Health Insurance Coverage'' by calling (410) 786–1565. Information on HIPAA's nondiscrimination rules and other recent health care laws is also available on the Department of Labor's website (http://www.dol.gov/dol/pwba) and the Department of Health and Human Services' website (http://hipaa.hcfa.gov).

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, was enacted on August 21, 1996. HIPAA amended the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974 (ERISA), and the Public Health Service Act (PHS Act) to provide for, among other things, improved portability and continuity of health coverage. HIPAA added section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act, which prohibit discrimination in health coverage. Interim final rules implementing the HIPAA provisions were first made available to the public on April 1, 1997 (published in the **Federal Register** on April 8, 1997, 62 FR 16894) (April 1997 interim rules). On December 29, 1997, the Departments published a clarification of the April 1997 interim rules as they relate to individuals who were denied coverage before the effective date of HIPAA on the basis of any health factor (62 FR 67689).

In the preamble to the April 1997 interim rules, the Departments invited

[1] References in this preamble to a specific paragraph in the interim regulations are to paragraphs in each of the three sets of regulations being published as part of this document. Specifically, references are to paragraphs in 26 CFR 54.9802–1 and 26 CFR 54.9802–1T (see discussion and table in ''C. Format of Regulations'' below), 29 CFR 2590.702, and 45 CFR 146.121.

comments on whether additional guidance was needed concerning—

- The extent to which the statute prohibits discrimination against individuals in eligibility for particular benefits;
- The extent to which the statute may permit benefit limitations based on the source of an injury;
- The permissible standards for defining groups of similarly situated individuals;
- Application of the prohibitions on discrimination between groups of similarly situated individuals; and
- The permissible standards for determining bona fide wellness programs.

In the preamble to the April 1997 interim rules, the Departments stated that they intend to issue further regulations on the nondiscrimination rules and that in no event would the Departments take any enforcement action against a plan or issuer that had sought to comply in good faith with section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act before the additional guidance is provided. Accordingly, with the issuance of these interim regulations, the Departments have determined that the period for nonenforcement in cases of good faith compliance ends in accordance with the rules described in paragraph (i) of these interim regulations.[2] However, because the interim regulations do not include a discussion of bona fide wellness programs (see proposed rules relating to bona fide wellness programs published elsewhere in this issue of the **Federal Register**), the period for good faith compliance continues with respect to those provisions until further guidance is issued.

II. Overview of the Regulations

Section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act (the HIPAA nondiscrimination provisions) establish rules generally prohibiting group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries. These interim regulations interpret the HIPAA nondiscrimination provisions. Among other things, the interim regulations—

- Explain the application of these provisions to benefits;
- Clarify the relationship between the HIPAA nondiscrimination provisions and the HIPAA preexisting condition exclusion limitations;
- Explain the application of these provisions to premiums;
- Describe similarly situated individuals;
- Explain the application of these provisions to actively-at-work and nonconfinement clauses; and
- Clarify that more favorable treatment of individuals with medical needs generally is permitted.

Described elsewhere in this issue of the **Federal Register** are proposed standards for defining bona fide wellness programs.

Of course, plans and benefits that are not subject to the HIPAA portability provisions (set forth in Chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and title XXVII of the PHS Act) are not subject to the HIPAA nondiscrimination requirements. Accordingly, the following plans and benefits are not subject to the HIPAA nondiscrimination requirements: benefits that qualify under the HIPAA portability provisions as excepted benefits; plans with fewer than two participants who are current employees on the first day of the plan year;[3] and self-funded non-Federal governmental plans that elect, under 45 CFR 146.180, to be exempt from these nondiscrimination requirements. In addition, under a proposed regulation published by the Department of the Treasury and described elsewhere in this issue of the **Federal Register**, certain church plans are treated as not violating the general HIPAA nondiscrimination provisions if the plan requires evidence of good health for the coverage of certain individuals.

Health Factors

The HIPAA nondiscrimination provisions set forth eight health status-related factors. The interim regulations refer to these as ''health factors.'' The eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. These terms are largely overlapping and, in combination, include any factor related to an individual's health.

Evidence of insurability. Several commenters urged that the health factor ''evidence of insurability'' be interpreted to prohibit plans and issuers from denying coverage to individuals who engage in certain types of activities. Commenters cited language in the conference report that states, ''The inclusion of evidence of insurability in the definition of health status is intended to ensure, among other things, that individuals are not excluded from health care coverage due to their participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing and other similar activities.'' H.R. Conf. Rep. No. 736, 104th Cong., 2d Sess. 186 (1996). The interim regulations clarify that evidence of insurability includes participation in activities listed in the conference report. In addition, the interim regulations incorporate the statutory clarification that evidence of insurability includes conditions arising out of acts of domestic violence. See also the discussion below concerning source-of-injury restrictions under the heading ''Application to Benefits.''

Late enrollees and special enrollees. Some commenters asked whether treating late enrollees differently from other enrollees is discrimination based on one or more health factors. HIPAA was designed to encourage individuals to enroll in health coverage when first eligible and to maintain coverage for as long as they continue to be eligible. Permitting plans and issuers to treat late enrollees less favorably than other enrollees is consistent with this objective. The interim regulations clarify that the decision whether to elect health coverage, including the time an individual chooses to enroll, such as late enrollment, is not itself within the scope of any health factor. Thus, the interim regulations permit plans and issuers to treat late enrollees differently from similarly situated individuals who enroll when first eligible.

Although the HIPAA nondiscrimination requirements do not prohibit different treatment of special enrollees, any differential treatment would violate the HIPAA special enrollment requirements. These interim regulations provide a cross-reference to the HIPAA regulations requiring special enrollees to be treated the same as individuals who enroll when first eligible.

Prohibited Discrimination in Rules for Eligibility

These interim regulations provide that group health plans and group health insurance issuers generally may not establish any rule for eligibility of any individual to enroll for benefits under the terms of the plan or group health insurance coverage that discriminates based on any health factor that relates to that individual or a dependent of that individual. Under these interim

[2] See footnote 1.

[3] However, a State may impose the requirements of the HIPAA portability provisions, in whole or in part, on health insurance coverage sold to groups that contain fewer than 2 current employees on the first day of the plan year. *See* sections 2723 and 2791(e) of the PHS Act.

regulations, rules for eligibility include, but are not limited to, rules relating to enrollment, the effective date of coverage, waiting (or affiliation) periods, late and special enrollment, eligibility for benefit packages (including rules for individuals to change their selection among benefit packages), benefits (as described below under the heading ''Application to Benefits''), continued eligibility, and terminating coverage of any individual under the plan.

The rules for eligibility apply in tandem with the rules describing similarly situated individuals (described below under the heading ''Similarly Situated Individuals'') to prevent discrimination in eligibility based on any health factor. Thus, while it is permissible for a plan or issuer to impose waiting periods of different lengths on different groups of similarly situated individuals, a plan or issuer would violate the interim regulations if it imposed a longer waiting period for individuals within the same group of similarly situated individuals based on the higher claims of those individuals (or based on any other adverse health factor of those individuals).

While the interim regulations clarify that late enrollment itself is not within the scope of any health factor, eligibility for late enrollment comes within the scope of rules for eligibility under which discrimination based on one or more health factors is prohibited. The effect of these rules is to permit plans or issuers to treat late enrollees differently from individuals who enroll when first eligible but to prohibit plans and issuers from distinguishing among applicants for late enrollment based on any health factor of the applicant. Thus, a plan could impose an 18-month preexisting condition exclusion on late enrollees while imposing no preexisting condition exclusion on individuals who enroll in the plan when first eligible, but a plan would violate the interim regulations if it conditioned the ability to enroll as a late enrollee on the passing of a physical examination (or on any other health factor of the individual, such as having incurred health claims during a past period below a certain dollar amount).

Application to Benefits

General rules. The extent to which the statutory language prohibits discrimination against individuals in eligibility for particular benefits is subject to a wide range of interpretations. At one extreme, the language could be interpreted as applying only to enrollment and to premiums. Under this interpretation, for example, it would be possible for a plan or issuer to impose a $100 lifetime limit on a particular individual with a history of high health claims (provided that the individual is permitted to enroll in the plan and is charged the same premium as similarly situated individuals), while imposing a $1 million lifetime limit on all other participants in the plan.

At the other extreme, the statutory language could be interpreted to mandate parity in health benefits. This interpretation would prevent plans and issuers from designing benefit packages that control costs and are responsive to employees' preferences for balancing additional benefits with additional costs.

In the preamble to the April 1997 interim rules, the Departments specifically invited comments on whether guidance was needed concerning this issue. The comments received ranged between these two extremes. The approach in these interim regulations takes into account the concerns expressed by commenters, as well as the conference report. Specifically, the conference report states that:

> It is the intent of the conferees that a plan cannot knowingly be designed to exclude individuals and their dependents on the basis of health status. However, generally applicable terms of the plan may have a disparate impact on individual enrollees. For example, a plan may exclude all coverage of a specific condition, or may include a lifetime cap on all benefits, or a lifetime cap on specific benefits. Although individuals with the specific condition would be adversely affected by an exclusion of coverage for that condition * * * such plan characteristics would be permitted as long as they are not directed at individual sick employees or dependents.

H.R. Conf. Rep. No. 736, 104th Cong., 2d Sess. 186–187 (1996).

The interim regulations clarify that they do not require a plan or issuer to provide coverage for any particular benefit to any group of similarly situated individuals. However, benefits provided under a plan or group health insurance coverage must be uniformly available to all similarly situated individuals. Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan or issuer may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan or issuer may impose annual, lifetime, or other limits on benefits and may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.[4] These interim regulations clarify that whether any plan provision with respect to benefits complies with the interim regulations does not affect whether the provision is permitted under the Americans with Disabilities Act (ADA), or any other law, whether State or federal.[5]

Accordingly, for example, a group health plan may apply a lifetime limit on all benefits provided to each participant covered under the plan. While this limitation on all benefits may adversely impact individuals with serious medical conditions, the limitation is permitted provided that it applies to all similarly situated individuals and is not directed at individual participants or beneficiaries. Similarly, a plan or issuer may establish a specific lifetime limit on the treatment of a particular condition (such as the treatment of temporomandibular joint syndrome (TMJ)) for all similarly situated individuals in the plan. Although individuals with TMJ may be adversely affected by this limitation, because benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and because the limit on benefits for TMJ applies to all similarly situated individuals, the limit is permissible.

Under these interim regulations, plans and issuers therefore have significant flexibility in designing benefits. However, to prevent plans and issuers from restricting benefits based on a

[4] For special rules that apply to cost-sharing mechanisms that are part of a bona fide wellness program, see the proposed regulations relating to bona fide wellness programs published elsewhere in this issue of the **Federal Register**.

[5] In this regard, the Equal Employment Opportunity Commission has commented, by letter of July 7, 1997, ''Title I of the ADA prohibits disability-based employment discrimination, including discrimination in fringe benefits such as health insurance plans.''

specific health factor of an individual under the plan, the interim regulations prohibit benefit restrictions, even if applied uniformly to all similarly situated individuals, from being directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. The interim regulations clarify that a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at individual participants and beneficiaries. This exception to the general facts and circumstances determination that a change is directed at an individual is necessary to preserve the flexibility of small employers that might otherwise be disproportionately affected and prevented from adopting changes in benefit design. If small employers are unable to modify future benefits to keep health coverage affordable, their alternative may be to eliminate health coverage entirely. At the same time, the exception reflects the common practice of modifying the terms of a plan on an annual basis. Finally, changes in benefit design that are effective earlier than the first day of the next plan year remain subject to a facts and circumstances determination regarding whether the change is directed at individual participants and beneficiaries.

An example illustrates that if an individual files a claim for the treatment of a condition, and shortly thereafter the plan is modified to restrict benefits for the treatment of the condition, effective before the beginning of the next plan year, the restriction would be directed at the individual based on a health factor (absent additional facts to indicate that the change was made independent of the claim) and the plan would violate these interim regulations.

Source-of-injury restrictions. While a person cannot be excluded from a plan for engaging in certain recreational activities (see previous discussion on evidence of insurability under the heading ''Health Factors''), benefits for a particular injury can, in some cases, be excluded based on the source of an injury. These plan restrictions are known as source-of-injury restrictions.[6] Under these interim regulations, if a plan or group health insurance coverage generally provides benefits for a type of injury, the plan or issuer may not use a source-of-injury restriction to deny benefits otherwise provided for treatment of the injury if it results from an act of domestic violence or a medical condition (including both physical and mental health conditions). An example in the interim regulations clarifies that benefits for injuries generally covered under the plan cannot be excluded merely because they were self-inflicted or were sustained in connection with a suicide or attempted suicide if the injuries resulted from a medical condition such as depression. Another example illustrates that a plan can nonetheless exclude benefits for injuries because they were sustained in connection with various recreational activities if the accident did not result from any medical condition (or from domestic violence).

The Relationship Between the HIPAA Nondiscrimination Provisions and the HIPAA Preexisting Condition Exclusion Provisions

Restrictions on benefits based on the fact that a medical condition was present before the first day of coverage discriminate against individuals based on one or more health factors. The statute nonetheless provides that the nondiscrimination provisions are intended to be construed in a manner consistent with the HIPAA provisions specifically allowing the application of preexisting condition exclusions. These latter provisions restrict the ability of a group health plan or group health insurance issuer to apply preexisting condition exclusions, both by restricting the circumstances under which an individual's condition is considered preexisting and by limiting the length of the exclusion period. The interim regulations clarify that a preexisting condition exclusion that satisfies the requirements of the HIPAA preexisting condition exclusion provisions is permitted under the HIPAA nondiscrimination requirements if the exclusion applies uniformly to individuals within the same group of similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. A plan amendment relating to a preexisting condition exclusion applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at individual participants or beneficiaries.

The examples illustrate that a typical preexisting condition exclusion permitted under the HIPAA preexisting condition exclusion requirements does not violate the HIPAA nondiscrimination requirements even though the exclusion inherently discriminates based on one or more health factors. The examples also illustrate that a plan nonetheless must apply the preexisting condition exclusion to similarly situated individuals in a uniform manner and cannot apply a longer preexisting condition exclusion period based on the submission of claims during the first part of the exclusion period.

Prohibited Discrimination in Premiums or Contributions

Under the interim regulations, a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require an individual, as a condition of enrollment or continued enrollment under the plan or group health insurance coverage, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual enrolled in the plan or group health insurance coverage, based on any health factor that relates to that individual or a dependent of that individual. Under the interim regulations, when determining an individual's premium or contribution rate, discounts, rebates, payments in kind, or other premium differential mechanisms are taken into account.[7]

In general, the interim regulations do not restrict the amount that an employer may be quoted or charged by an issuer (or, in the case of a multiemployer plan, by the plan) for coverage of a group of similarly situated individuals. However, the interim regulations prohibit certain billing practices because in many instances they could directly or indirectly result in an individual's being charged more than a similarly situated individual based on a health factor.

Some health insurance issuers that offer health insurance coverage in connection with a group health plan use billing practices with separate individual rates that vary based, in part, on the health factors of the individuals who are eligible to participate in the plan. This practice is generally known as list billing. List billing based on a

[6] A commenter pointed out that this type of restriction is distinct from two other restrictions sometimes referred to as ''source-of-injury restrictions''—(1) those based on the geographic location where the injury occurred, and (2) those based on when the injury occurred and whether other coverage was in effect.

[7] However, a group health plan or a health insurance issuer offering group health insurance coverage may establish premium or contribution differentials through a bona fide wellness program. (See proposed regulations relating to bona fide wellness programs published elsewhere in this issue of the **Federal Register**).

health factor is prohibited under the interim regulations.

The HIPAA nondiscrimination requirements do not prohibit an issuer from considering all relevant health factors of individuals in order to establish aggregate rates for coverage provided under the group health plan. However, an individual may not be required to pay a higher premium based on any health factor of the individual. Under the interim regulations, an issuer (or a multiemployer plan) may not quote or charge an employer different premium rates on an individual-by-individual basis in a group of similarly situated individuals based on any health factor of the individuals, even if the employer does not pass the different rates through to the individuals. If an issuer wishes to increase rates to cover the additional exposure to expenses that may result from an individual's health factor, the issuer must blend the increase into an overall group rate and then quote or charge a higher per-participant rate. Nonetheless, the prohibition on the practice of list billing based on a health factor does not restrict communications between issuers and plans regarding rate calculations.

Similarly Situated Individuals

The statutory HIPAA nondiscrimination requirements clarify that the general rule prohibiting discrimination in eligibility does not prevent a group health plan or group health insurance coverage from establishing limitations or restrictions on the amount, level, extent, or nature of benefits for ''similarly situated individuals'' enrolled in the plan or coverage. The statutory rule prohibiting discrimination in charging individuals premiums or contributions prohibits a plan or issuer from requiring any individual, based on any health factor of that individual or a dependent of that individual, to pay a premium or contribution that is greater than the premium or contribution required of a ''similarly situated individual.'' In the preamble to the April 1997 interim rules, the Departments requested comments both on the permissible standards for defining groups of similarly situated individuals and on the application of the prohibitions on discrimination between groups of similarly situated individuals.

Many commenters suggested that discrimination between groups of similarly situated individuals should be permitted, with the caveat that it should not be permissible to define a group based on a health factor. These interim regulations provide that the nondiscrimination rules apply only within a group of similarly situated individuals. Thus, these interim regulations do not prohibit discrimination between or among groups of similarly situated individuals. However, these interim regulations also provide that if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries, the classification is not permitted. This is intended to be a broad anti-abuse standard that applies based on the relevant facts and circumstances of each case.

The permissibility of discrimination between or among groups of similarly situated individuals increases the possibility of abuse in establishing groups of similarly situated individuals. Most commenters addressing this issue focused on the classification of participants and suggested that classifications should be based on work activities and not on a health factor or on activities unrelated to employment. The interim regulations provide generally that participants may be treated as two or more groups of similarly situated individuals if the distinction between or among the groups is based on a bona fide employment-based classification consistent with the employer's usual business practice. The validity of a category as a bona fide employment-based classification is determined based on all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to the anti-abuse standard (described in the preceding paragraph), the interim regulations allow distinctions to be made based on full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations.

Some commenters expressed concern that allowing similarly situated individuals to be determined based on occupation or geographic location would allow plans and issuers to create artificial classifications, ostensibly based on occupation or geographic location, that are actually designed to discriminate based on a health factor of an individual or individuals. These interim regulations permit bona fide classifications based on occupation or geographic location. In this connection, commenters had two principal concerns. First, there was a concern about reclassifications targeting unhealthy individuals. For example, a participant receiving expensive medical treatment might be reclassified to a separate employment category either with reduced health benefits or none at all. The broad anti-abuse standard of these interim regulations is intended, among other things, to prohibit reclassifications directed at individuals such as this.

A second concern that commenters had was that plans and issuers might design health benefits differently for employees in different occupations or geographic locations based, at least in part, on the health factors of these groups of individuals. One example is a plan that offers fewer benefits to employees in one occupation than to employees in another occupation at least in part because of the higher average historical claims of the employees in the first occupation. A second example is a plan that charges employees in one area more than employees in another area at least in part because the cost of medical care is generally higher in the first area. The statute and legislative history appear to allow this practice, and thus these interim regulations do not prohibit the provision of different health benefits for employees in different occupations or geographic locations, based at least in part on the health factors of the group as a whole, if the classifications are not directed at individual participants or beneficiaries based on a health factor of the participants or beneficiaries.

These interim regulations also permit plans and issuers, in certain circumstances, to treat beneficiaries as different groups of similarly situated individuals. Beneficiaries may be treated as a group of similarly situated individuals separate from participants, and different treatment is permitted among beneficiaries based on bona fide employment-based classifications of the participants through whom the beneficiaries are receiving coverage. Thus, if the plan provides different benefits to full-time employees than to part-time employees, then it may also provide different benefits to dependents of full-time employees than to dependents of part-time employees. Similarly, different treatment is permitted based on the beneficiary's relationship to the participant (for example, as a spouse or as a dependent child). Different treatment is also permitted based on the beneficiary's marital status, based on a dependent

child's age or student status, or based on any other factor if the factor is not a health factor.

The rules in these interim regulations allowing the different treatment of individuals in different groups of similarly situated individuals are distinct from rules requiring that qualified beneficiaries under a COBRA continuation provision [8] have available the same coverage as similarly situated non-COBRA beneficiaries. Although these interim regulations would not prohibit making benefit packages available to non-COBRA beneficiaries (such as current employees) that are not made available to COBRA qualified beneficiaries (such as former employees), the COBRA continuation provisions prohibit such a difference.

Finally, all of the requirements relating to determining groups of similarly situated individuals are subject to other rules in these interim regulations permitting favorable treatment of individuals with certain adverse health factors (discussed below under the heading ''More Favorable Treatment of Individuals with Adverse Health Factors Permitted'').

Nonconfinement Provisions

Some group health plans and health insurance issuers refuse to provide benefits to an individual based on the individual's confinement to a hospital or other health care institution at the time coverage otherwise would become effective. Plan provisions like these are often called ''nonconfinement clauses.'' Any reasonable interpretation or application of the statutory HIPAA nondiscrimination provisions prohibits a plan or issuer from imposing a nonconfinement clause.[9] Thus, a plan or issuer may not deny the eligibility of any individual to enroll for benefits or charge any individual a higher premium (or contribution) because the individual, or a dependent of the individual, is confined to a hospital or other health care institution. In addition, some plans and issuers refuse to provide benefits to an individual based on an individual's inability to engage in normal life activities. A plan or issuer generally may not deny the eligibility of any individual to enroll for benefits or charge any individual a higher premium (or contribution) based on any individual's ability to engage in normal life activities. However, these interim regulations provide an exception that permits plans and issuers to distinguish among employees based on the performance of services. Although in practice nonconfinement clauses generally apply only to dependents, in some cases they apply also to employees. Thus, the interim regulations clarify that a nonconfinement clause would also be impermissible if applied to an employee.

These rules are of particular interest in the case of a group health plan switching coverage from one health insurance issuer to a succeeding health insurance issuer. In such a case, the HIPAA nondiscrimination provisions prohibit the succeeding issuer from denying eligibility to any individual due to confinement to a hospital or other health care institution because such a denial would discriminate in eligibility based on one or more health factors. The obligation of the succeeding issuer to provide coverage to such an individual does not preempt any obligation that the prior issuer may have under other applicable law, including State extension of benefits laws.

Actively-at-Work and Other Service Requirements

Some group health plans and health insurance issuers refuse to provide benefits to an individual if the individual is not actively at work on the day the individual would otherwise become eligible for benefits. Plan provisions like these are often called ''actively-at-work clauses.'' These interim regulations provide that a plan or issuer generally may not impose an ''actively-at-work clause.'' That is, these interim regulations prohibit a plan or issuer from denying the eligibility of any individual to enroll for benefits or charging any individual a higher premium or contribution based on whether an individual is actively at work (including whether an individual is continuously employed). However, an actively-at-work clause is permitted if individuals who are absent from work due to any health factor (for example, individuals taking sick leave) are treated, for purposes of health coverage, as if they are actively at work. Accordingly, plan provisions that delay enrollment until an individual is actively at work on a day following a waiting period (or for a continuous period) are prohibited unless absence from work due to any health factor is considered being actively at work.

These interim regulations also provide an exception for the first day of work to the general prohibition against actively-at-work clauses. Under the exception, a plan or issuer may require an individual to begin work before coverage may become effective.

The interim regulations explain the relationship between the rules governing actively-at-work clauses and the rules describing similarly situated individuals. Under the interim regulations, a plan or issuer is generally permitted to distinguish between groups of similarly situated individuals (provided the distinction is not directed at individual participants or beneficiaries based on a health factor). Examples illustrate that a plan or issuer may condition coverage on an individual's meeting the plan's requirement of working full-time (such as a minimum of 250 hours in a three-month period or 30 hours per week). In addition, a plan or issuer may terminate coverage for former employees while providing coverage to current employees without violating the HIPAA nondiscrimination provisions if the rules describing similarly situated individuals are satisfied, even if the former employee is unable to work due to a health factor. Similarly, a plan or issuer may charge a higher premium to employees no longer performing services than to employees currently performing services without violating the HIPAA nondiscrimination provisions if the rules describing similarly situated individuals are met. An example illustrates that the interim regulations would not, however, permit a plan or issuer to treat individuals on annual or bereavement leave better than individuals on sick leave because groups of similarly situated individuals cannot be established based on any health factor (including the taking of sick leave).

In any case, other federal or State laws, including the COBRA continuation provisions and the Family and Medical Leave Act of 1993 (FMLA), may require individuals to be offered coverage and set limits on the premium or contribution rate.

Bona Fide Wellness Programs

The HIPAA nondiscrimination provisions do not prevent a plan or issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention. Thus, there is an exception to the general rule prohibiting

[8] The term *COBRA continuation provision* is defined in 26 CFR 54.9801–2T, 29 CFR 2590.701–2, and 45 CFR 144.103.

[9] For an example illustrating that the imposition of a nonconfinement clause is not a good faith interpretation of the HIPAA nondiscrimination provisions, and the rule requiring that individuals denied enrollment without a good faith interpretation of the law be provided an opportunity to enroll, see the discussion below under the heading ''Transitional Rule for Individuals Previously Denied Coverage Based on a Health Factor.''

discrimination based on a health factor if the reward, such as a premium discount or waiver of a cost-sharing requirement, is based on participation in a program of health promotion or disease prevention. The April 1997 interim rules, these interim regulations, and proposed regulations published elsewhere in this issue of the **Federal Register** refer to programs of health promotion and disease prevention allowed under this exception as ''bona fide wellness programs.'' For a discussion of bona fide wellness programs, see the preamble to proposed regulations published elsewhere in this issue of the **Federal Register**.

More Favorable Treatment of Individuals With Adverse Health Factors Permitted

Many group health plans make certain periods of extended coverage available to employees no longer performing services only if the employee is unable to work due to disability, and many plans make coverage available to dependent children past a certain age only if the child is disabled. Some plans waive or reduce the required employee contribution for coverage if the employee or a member of the employee's immediate family is in a critical medical condition for a prolonged period. Disability and medical condition are listed in the statute as health factors, and several commenters recognized that, under one possible interpretation of the HIPAA nondiscrimination requirements, plan provisions or practices such as these would be impermissible. These commenters asked for guidance clarifying that plan provisions and practices like these would be permissible. Other commenters cited the rule under the COBRA continuation provisions permitting plans to require payment of a higher amount during the disability extension than during other periods of COBRA coverage and asked whether following this COBRA rule is permissible under the HIPAA nondiscrimination requirements.

Eligibility. These interim regulations permit plans and issuers to establish rules for eligibility favoring individuals based on an adverse health factor, such as disability. Thus, a plan or issuer does not violate the HIPAA nondiscrimination requirements by making extended coverage available to employees no longer providing services only if the employee is unable to work due to disability nor by making coverage available to dependent children past a certain age only if the child is disabled. Examples clarify this rule.

Premiums. These interim regulations also address the circumstances under which differential premiums (or contributions) may be charged to an individual based on an adverse health factor. These interim regulations permit plans and issuers to charge a higher rate in some situations and also a lower rate to individuals based on an adverse health factor, such as disability. A higher rate may be charged only in situations where the individual with the adverse health factor would not have coverage were it not for the adverse health factor. Thus, in a case where a plan or issuer makes extended coverage available to employees no longer performing services only if the employee is unable to work due to disability, the plan could require a higher payment from the employee only while the employee is receiving coverage under that special eligibility provision. However, the plan could not charge a disabled employee a higher rate than nondisabled employees while the disabled employee was still eligible under a generally-applicable eligibility provision, rather than the special extended coverage provision. Accordingly, under the interim regulations, a plan or issuer could charge a higher rate for COBRA coverage during the disability extension than for COBRA coverage outside the disability extension (and the result is the same if the extended coverage for disability is provided pursuant to State law or plan provision rather than pursuant to a COBRA continuation provision).[10]

Although charging a higher rate based on an adverse health factor is limited to the situation in which coverage would not be available but for the adverse health factor, under these interim regulations a plan or issuer is always permitted to charge an individual a lower rate based on an adverse health factor. Thus, even though an employee is receiving coverage under the same eligibility provision as other employees who are required to pay the full employee share of the premium, under the interim regulations it is permissible to waive or reduce the employee share of the premium if the employee or a family member is in critical medical condition for a prolonged period.

[10] This result is consistent with the result under the COBRA continuation provisions. Under those provisions, plans are generally permitted to require payment of up to 102 percent of the applicable premium but are permitted to require payment for coverage of a disabled qualified beneficiary of up to 150 percent of the applicable premium during the disability extension period.

No Effect on Other Laws

Compliance with these interim regulations is not determinative of compliance with any other provision of ERISA, or any other State or federal law, including the Americans with Disabilities Act. Therefore, while these interim regulations generally do not impose any new disclosure requirements on plans or issuers, other applicable law continues to apply. For example, under Title I of ERISA, administrators of ERISA-covered group health plans are required to provide participants and beneficiaries with a summary plan description that is sufficiently accurate and comprehensive to reasonably apprise such participants and beneficiaries of their rights and obligations under the plan.[11] In addition, some courts have held that fiduciaries of ERISA-covered group health plans are obligated to ensure that plan documents and disclosures are consistent with applicable disclosure requirements and do not serve to mislead or misinform participants and beneficiaries concerning their rights and obligations under the plans in which they participate.[12] Fiduciaries are advised to take steps to ensure that plan disclosures are accurate and are not misleading.

These interim regulations are also not determinative of compliance with the COBRA continuation provisions, or any other State or federal law, such as the Americans with Disabilities Act.

Applicability Date

These interim regulations generally apply for plan years beginning on or after July 1, 2001 (although some provisions apply earlier, as discussed below under the heading ''III. Format of Regulations''). As noted above, in the preamble to the April 1997 interim rules the Departments stated that they intended to issue further regulations on the statutory nondiscrimination rules. That preamble also stated that in no event would the Departments take any enforcement action against a plan or issuer that had sought to comply in good faith with the statutory nondiscrimination provisions before the additional guidance was issued. The Departments will not take any enforcement action against a plan or issuer with respect to efforts to comply in good faith with the statutory nondiscrimination provisions before the first plan year beginning on or after July 1, 2001. (See the description of

[11] See ERISA section 102, and the Department of Labaor's regulations issued thereunder.

[12] See *Varity Corp* v. *Howe*, 516 U.S. 489, 506 (1996).

transitional rules immediately below regarding certain interpretations that are not good faith interpretations of the statutory nondiscrimination requirements.) Upon the applicability of these regulations, however, good faith efforts to comply with the statutory provisions addressed by these interim regulations may not be sufficient to avoid adverse enforcement actions by the Departments. Therefore, for plan years beginning on or after July 1, 2001, plans and issuers must comply with the requirements of these regulations in order to avoid adverse enforcement actions. As discussed earlier, under the heading ''Background,'' the period for good faith compliance continues with respect to bona fide wellness programs until further guidance is issued.

Transitional Rules for Individuals Previously Denied Coverage Based on a Health Factor

The April 1997 interim rules clarified that a plan or issuer violates the HIPAA nondiscrimination requirements if it requires an individual to pass a physical examination as a condition for enrollment, even if the condition is imposed only on late enrollees. The HIPAA nondiscrimination requirements apply both to eligibility and continued eligibility of any individual to enroll under a plan. Consequently, once HIPAA became effective with respect to a plan or health insurance issuer, it was a violation of the nondiscrimination requirements to continue to deny an individual eligibility to enroll if the reason the individual was denied enrollment previously was due to one or more health factors (such as requiring the individual to pass a physical examination).

On December 29, 1997, the Departments issued in the **Federal Register** a clarification of the April 1997 interim rules relating to individuals who were denied coverage due to a health factor before the effective date of HIPAA (62 FR 67689). The clarification restates the requirement of the April 1997 interim rules that an individual cannot be denied coverage based on a health factor on or after the effective date of HIPAA. The clarification then states that individuals to whom coverage had not been made available before the effective date of HIPAA based on a health factor and who enrolled when first eligible on or after the effective date of the HIPAA nondiscrimination provisions could not be treated as a late enrollee for purposes of the HIPAA preexisting condition exclusion provisions. Under the clarification, individuals to whom coverage had not been made available include any individual who did not apply for coverage because it was reasonable to believe that the application would have been futile. The rules in the clarification apply whether or not the plan offered late enrollment.

Neither the April 1997 interim rules nor the December 1997 guidance clearly addressed the situation where an individual was denied only late enrollment based on a health factor prior to the effective date of HIPAA and, by the effective date of HIPAA, the plan eliminated late enrollment. For example, prior to HIPAA many plans and issuers allowed individuals to enroll when first eligible without regard to health status, but allowed late enrollees to enroll only if they could pass a physical examination (or present evidence of good health). Upon the effective date of HIPAA, some of these plans and issuers eliminated late enrollment.

Any plan or issuer that permitted these individuals to enroll once the HIPAA nondiscrimination provisions took effect, of course, is in compliance with this provision of the nondiscrimination rules. In contrast, a plan or issuer that continued to deny coverage to these individuals may have done so based on a good faith interpretation of the statute and the Departments' published guidance. For example, a plan or issuer might reasonably have thought that HIPAA did not require it to remedy pre-HIPAA denials of late enrollment based on a health factor for individuals who could have enrolled initially without regard to their health if the plan or issuer eliminated late enrollment by the effective date of HIPAA.

The interim regulations provide transitional rules for situations where coverage was denied to individuals based on one or more health factors, both where the denial was based on a good faith interpretation of the statute or the Departments' published guidance and where it was not. In either event, a safe harbor provides that the Departments will not take any enforcement action with respect to such a denial of coverage if the plan or issuer complies with the transitional rules.

Where the denial was not based on a good faith interpretation, the interim regulations provide that the plan or issuer is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days. This opportunity must be presented not later than March 9, 2001. If the opportunity is presented within the first plan year beginning on or after the effective date of the statutory HIPAA nondiscrimination rules, the enrollment must be effective within that plan year. If this enrollment opportunity is presented after such plan year, the individual must be given an option to have coverage effective either (1) prospectively from the date the plan receives a request for enrollment in connection with the enrollment opportunity or (2) retroactively to the first day of the first plan year beginning on HIPAA's effective date for the plan (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan).

The reason for giving the individual the opportunity to elect retroactive coverage is to make the individual whole; that is, to put the individual in the same financial condition that the individual would have been in had the individual not been denied enrollment. Thus, if the individual elects retroactive coverage, the plan or issuer may require the individual to pay premiums or contributions for the retroactive period (but the plan or issuer cannot charge interest on that amount).

The rule differs for situations where coverage was denied to individuals based on one or more health factors but where the denial was based on a good faith interpretation of the statute or the Departments' prior published guidance. In those situations, these interim regulations require plans and issuers to give the individuals an opportunity to enroll that continues for at least 30 days and with coverage effective not later than July 1, 2001.

In both situations (whether the denial of coverage was or was not based on a good faith interpretation), the interim regulations also clarify that, once enrolled, these individuals cannot be treated as late enrollees. The individual's enrollment date under the plan is the effective date of HIPAA (or, if later, the date the individual would have otherwise been eligible to enroll). In addition, any period between an individual's enrollment date and the effective date of coverage is treated as a waiting period. Thus, for example, with respect to a calendar year plan that is not collectively bargained, an individual who was previously denied late enrollment due to a health factor before the effective date of HIPAA has an enrollment date of January 1, 1998 (HIPAA's effective date for that plan) and a waiting period that begins on that date. Moreover, because any waiting period must begin on the individual's enrollment date, January 1, 1998, and the maximum preexisting exclusion period that can be applied is 12 months,

individuals who enroll in the plan on July 1, 2001 cannot be subject to any preexisting condition exclusion period.

Special Transitional Rule for Self-Funded Non-Federal Governmental Plans Exempted Under 45 CFR 146.180

The sponsor of a self-funded non-Federal governmental plan may elect under section 2721(b)(2) of the PHS Act and 45 CFR 146.180 to exempt its group health plan from the nondiscrimination requirements of section 2702 of the PHS Act and 45 CFR 146.121. If the plan sponsor subsequently chooses to bring the plan into compliance with these nondiscrimination requirements, the plan must provide notice to that effect to individuals who were denied enrollment based on one or more health factors, and afford those individuals an opportunity, that continues for at least 30 days, to enroll in the plan. (An individual is considered to have been denied coverage if he or she failed to apply for coverage because, given an exemption election under 45 CFR 146.180, it was reasonable to believe that an application for coverage would have been denied based on a health factor.) The notice must specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan comes into compliance. The plan may not treat the individual as a late enrollee or a special enrollee. Coverage must be effective no later than the date the exemption election under 45 CFR 146.180 (with regard to these nondiscrimination requirements) no longer applies, or July 1, 2001 (if later) and the plan was acting in accordance with a good faith interpretation of the statutory HIPAA nondiscrimination provisions and guidance published by the Health Care Financing Administration.

III. Format of Regulations

Final and Temporary Treasury Regulations

The Department of the Treasury is issuing a portion of these regulations as final regulations and a portion as temporary and cross-referencing proposed regulations. The April 1997 interim rules were originally issued by Treasury in the form of temporary and cross-referencing proposed regulations. Under section 7805(e)(2) of the Code, however, any temporary regulation issued under the Code expires within three years after the date issued. Treasury is issuing final regulations that restate the rules relating to the HIPAA nondiscrimination requirements from the April 1997 regulations without significant modification. The final regulations apply March 9, 2001. Table 1 identifies which paragraphs of the final regulation issued today correspond to which paragraphs of the April 1997 regulation. New guidance being published today by Treasury is being issued as temporary and cross-referencing proposed regulations. This guidance will apply to group health plans beginning with the first plan year on or after July 1, 2001. (These new temporary regulations will also expire after three years pursuant to section 7805(e) of the Code.)

TABLE 1.—COMPARISON OF TREASURY'S APRIL 1997 REGULATIONS WITH TREASURY'S FINAL REGULATIONS

April 1997 regulations	Final regulation under § 9802
§ 54.9802–1T(a)(1)	§ 54.9802–1(a)(1),(2); (b)(1)
§ 54.9802–1T(a)(2)(i)	§ 54.9802–1(b)(2)(i)(A)
§ 54.9802–1T(a)(3)	[The corresponding provision is in the new temporary regulations.]
§ 54.9802–1T(a)(4)	§ 54.9802–1(b)(1)(iii)
§ 54.9802–1T(b)(1)	§ 54.9802–1(c)(1)(i)
§ 54.9802–1T(b)(2)(i)	§ 54.9802–1(c)(2)(i)
§ 54.9802–1T(b)(2)(ii)	§ 54.9802–1(b)(2)(i); (c)(3)
§ 54.9802–1T(b)(3)	[The corresponding provision is in the new proposed regulations for wellness programs.]

Interim Final Labor and HHS Regulations

The guidance issued by the Departments of Labor (Labor) and Health and Human Services (HHS) in April 1997 is not subject to a statutory expiration date. Accordingly, the Labor and HHS guidance is being published as interim final regulations. These regulations contain two applicability dates that parallel the two separate applicability dates in the Treasury guidance. Table 2 identifies which paragraphs of the interim final regulation issued today are applicable on March 9, 2001 and which paragraphs apply on or after July 1, 2001.

TABLE 2.—APPLICABILITY DATES FOR THE INTERIM FINAL REGULATIONS

Subject	Paragraph of the interim final regulations	Applies 3/9/01	Applies plan years beginning on or after 7/1/2001
Health factors	(a)(1)	✔	
Health factors—Evidence of insurability—Conditions arising out of an act of domestic violence.	(a)(2)(i)	✔	
Health factors—Evidence of insurability—Participation in certain activities.	(a)(2)(ii)		✔
Health factors—The decision whether health coverage is elected	(a)(3)		✔
Prohibited discrimination in rules for eligibility—General rule	(b)(1)(i)	✔	
Prohibited discrimination in rules for eligibility—Rules for eligibility described.	(b)(1)(ii)		✔
Prohibited discrimination in eligibility—General rule—Example 1	(b)(1)(iii) Example 1	✔	
Prohibited discrimination in eligibility—General rule—Examples 2 through 4.	(b)(1)(iii) Examples 2 through 4		✔
Prohibited discrimination in eligibility—Application to benefits—No benefits mandated.	(b)(2)(i)(A)	✔	

TABLE 2.—APPLICABILITY DATES FOR THE INTERIM FINAL REGULATIONS—Continued

Subject	Paragraph of the interim final regulations	Applies 3/9/01	Applies plan years beginning on or after 7/1/2001
Prohibited discrimination in eligibility—Application to benefits—Nondiscriminatory benefit restrictions permitted.	(b)(2)(i)(B), (C), & (D)		✔
Prohibited discrimination in eligibility—Application to benefits—Certain cost-sharing mechanisms.	(b)(2)(ii)	✔	
Prohibited discrimination in eligibility—Application to benefits—Source-of-injury exclusions.	(b)(2)(iii)		✔
Prohibited discrimination in eligibility—Application to benefits—Relationship to HIPAA preexisting condition exclusion rules.	(b)(3)		✔
Prohibited discrimination in premiums or contributions—General rule	(c)(1)(i)	✔	
Prohibited discrimination in premiums or contributions—Determining an individual's premium rate.	(c)(1)(ii)		✔
Prohibited discrimination in premiums or contributions—Group rating on health factors not restricted.	(c)(2)(i)	✔	
Prohibited discrimination in premiums or contributions—List billing based on a health factor prohibited.	(c)(2)(ii) & (iii)		✔
Prohibited discrimination in premiums or contributions—Exception for bona fide wellness programs.	(c)(3)	✔	
Similarly situated individuals	(d)		✔
Nonconfinement and actively-at-work provisions	(e)		✔
Bona fide wellness programs	(f) [Reserved.]	See proposed regulations published elsewhere in this **Federal Register**.	
More favorable treatment of individuals with adverse health factors permitted.	(g)		✔
No effect on other laws	(h)		✔

IV. Interim Final Regulations With Request for Comments

The principal purpose of these interim final regulations is to provide additional guidance on how to comply with the HIPAA nondiscrimination provisions contained in section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act. Code section 9833, ERISA section 734, and PHS Act section 2792 authorize the Secretaries of the Treasury, Labor, and HHS to issue any interim final rules as the Secretaries deem are appropriate to carry out certain provisions of HIPAA, including the nondiscrimination provisions. As explained below, the Secretaries have determined that these regulations should be issued as interim final rules with requests for comments.

HIPAA was enacted in August of 1996. The Secretaries first issued interim final rules providing guidance on HIPAA's nondiscrimination provisions in April of 1997. In publishing this guidance, the Secretaries relied on the authority granted in section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act, as well as other authority including section 101(g)(4) of HIPAA and section 505 of ERISA. As part of the April 1997 rulemaking, the Secretaries requested comments on whether additional guidance was needed concerning the extent to which the statutory HIPAA nondiscrimination provisions prohibit discrimination against individuals in eligibility for particular benefits; the extent to which the statute may permit benefit limitations based on the source of an injury; the permissible standards for defining groups of similarly situated individuals; the application of the prohibitions on discrimination between groups of similarly situated individuals; and the permissible standards for determining bona fide wellness programs. Numerous comments were received in response to this request.

After evaluating all of the comments, and after speaking with various interested parties in the course of an extensive educational outreach campaign, the Departments have developed these comprehensive regulations. Among other things, the comments reflected the need for more comprehensive guidance on the application of the nondiscrimination provisions. In the period since HIPAA was enacted and the April 1997 regulations were issued, numerous issues have arisen concerning how plans and issuers should apply the nondiscrimination provisions. In addition, the number of comments and the breadth of issues raised demonstrates that these regulations should go into effect on an interim basis pending receipt of further comments. This need to act on an interim basis is also supported by the General Accounting Office's request that the Departments "promptly complete regulations related to HIPAA's nondiscrimination provisions" (GAO/HEHS 00–85). Therefore, the Departments have determined that it is appropriate to issue the guidance on an interim final basis, with the exception of the bona fide wellness program provisions.[13] With respect to these last provisions, the Departments would like to better develop the administrative record before any provisions regarding such programs go into effect.

The Secretaries believe that this period of interim effectiveness will provide ample opportunity for the regulated community to comment specifically on this comprehensive guidance, providing a sound basis for developing final rules. The Departments are seeking comments from all those affected by these regulations, and the Departments will consider such comments and will reevaluate these regulations following the comment period in the same way that it would if the regulations had been published in proposed form. Based on such comments and other information obtained through the administration of the nondiscrimination requirements, the Departments will make any necessary modifications to the regulations when they are issued in final form.

[13] See proposed rules relating to bona fide wellness programs published elsewhere in this issue of the **Federal Register**.

V. Economic Impact and Paperwork Burden

Summary—Department of Labor and Department of Health and Human Services

HIPAA's nondiscrimination provisions generally prohibit group health plans and group health plan issuers from discriminating against individuals in eligibility or premium on the basis of health status factors. The Departments crafted this regulation to secure these protections as intended by Congress in as economically efficient a manner as possible, and believe that the economic benefits of the regulation outweigh its costs.

The primary economic benefits associated with securing HIPAA's nondiscrimination provisions derive from increased access to affordable group health plan coverage for individuals with health problems. Increased access benefits both newly covered individuals and society at large. It fosters expanded insurance coverage, timelier and fuller medical care, better health outcomes, and improved productivity and quality of life. This is especially true for the individuals most affected by HIPAA's nondiscrimination provisions—those with adverse health conditions. Denied insurance, individuals in poorer health are more likely to suffer economic hardship, to forgo badly needed care for financial reasons, and to suffer adverse health outcomes as a result. For them, gaining insurance is more likely to mean gaining economic security, receiving timely, quality care, and living healthier, more productive lives.

Additional economic benefits derive directly from the improved clarity provided by the regulation. The regulation will reduce uncertainty and costly disputes and promote confidence in health benefits' value, thereby improving labor market efficiency and fostering the establishment and continuation of group health plans.

The Departments estimate that the cost of plans to implement amendments in order to comply with this regulation, revise materials accordingly, and provide notices of opportunities to enroll as required by the regulation will amount to less than $19 million. This is a one-time cost distinguishable from the transfer that will result from the self-implementing requirements of HIPAA's nondiscrimination provisions and the discretion exercised by the Departments in this regulation.

Such a transfer occurs when resources are redistributed without any direct change in aggregate social welfare. In this instance, the premium and claims cost incurred by group health plans to provide coverage under HIPAA's statutory nondiscrimination provisions to individuals previously denied coverage or offered restricted coverage based on health factors are offset by the commensurate or greater benefits realized by the newly eligible participants on whose behalf the premiums or claims are paid. Although the Departments are not aware of any published estimates of transfers attributable to HIPAA's statutory nondiscrimination provisions, a rough attempt to gauge the order of magnitude of this transfer suggests that it may amount to more than $400 million annually, which is a small fraction of 1 percent of total expenditures by group plans. The regulation clarifies at the margin exactly what practices are permitted or prohibited by these provisions, and may have the effect of slightly increasing the amount of this transfer.

Executive Order 12866—Department of Labor and Department of Health and Human Services

Under Executive Order 12866, the Departments must determine whether a regulatory action is ''significant'' and therefore subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising 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 the Executive Order, it has been determined that this action raises novel policy issues arising out of legal mandates. In addition, the magnitude of the transfer that arises from the implementation of HIPAA's statutory nondiscrimination provisions is estimated to exceed $100 million. Therefore, this notice is ''significant'' and subject to OMB review under Sections 3(f)(1) and 3(f)(4) of the Executive Order. Consistent with the Executive Order, the Departments have assessed the costs and benefits of this regulatory action. The Departments' assessment, and the analysis underlying that assessment, is detailed below. The Departments performed a comprehensive, unified analysis to estimate the costs and benefits attributable to the interim regulation for purposes of compliance with the Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act.

1. Statement of Need for Proposed Action

These interim regulations are needed to clarify and interpret the HIPAA nondiscrimination provisions (prohibiting discrimination against individual participants and beneficiaries based on health status) under section 702 of the Employee Retirement Income Security Act of 1974 (ERISA), section 2702 of the Public Health Service Act, and section 9802 of the Internal Revenue Code of 1986. The provisions are needed to ensure that group health plans and group health insurers and issuers do not discriminate against individuals, participants, and beneficiaries based on any health factors with respect to health care coverage and premiums. Additional guidance was required to explain the application of the statute to benefits, clarify the relationship between the HIPAA nondiscrimination provisions and the HIPAA preexisting condition exclusion limitations, explain the applications of these provisions to premiums, describe similarly situated individuals, explain the application of the provisions to actively-at-work and nonconfinement clauses, clarify that more favorable treatment of individuals with medical needs generally is permitted, and describe plans' and issuers' obligations with respect to plan amendments.

2. Costs and Benefits

The primary economic benefits associated with the HIPAA nondiscrimination provisions derive from increased access to affordable group health plan coverage for individuals with health problems. Expanding access benefits both newly covered individuals and society at large by fostering expanded insurance coverage, timelier and fuller medical care, better health outcomes, and improved productivity and quality of life. Additional economic benefits derive directly from the improved clarity provided by the regulation. By clarifying employees' rights and plan sponsors' obligations under HIPAA's

nondiscrimination provisions, the regulation will reduce uncertainty and costly disputes and promote confidence in health benefits' value, thereby improving labor market efficiency and fostering the establishment and continuation of group health plans.

The Departments estimate that the cost to plans to implement amendments in order to comply with this regulation, revise materials accordingly, and provide notices of opportunities to enroll as required by the regulation will amount to less than $19 million. This is a one-time cost distinguishable from the transfer that will result from the self-implementing requirements of HIPAA's nondiscrimination provisions and the discretion exercised by the Departments in this regulation.

Such a transfer occurs when resources are redistributed without any direct change in aggregate social welfare. In this instance, the premium and claims cost incurred by group health plans to provide coverage under HIPAA's statutory nondiscrimination provisions to individuals previously denied coverage or offered restricted coverage based on health factors are offset by the commensurate or greater benefits realized by the newly eligible participants on whose behalf the premiums or claims are paid. Although the Departments are not aware of any published estimates of transfers attributable to HIPAA's statutory nondiscrimination provisions, a rough attempt to gauge the order of magnitude of this transfer suggests that it may amount to more than $400 million annually. The regulation clarifies at the margin exactly what practices are permitted or prohibited by these provisions, and may have the effect of slightly increasing the amount of this transfer. The Departments note that this transfer is the direct reflection of the intent and beneficial effect of HIPAA's nondiscrimination provisions: increasing access to affordable group health plan coverage for individuals with health problems. They also note that even the full transfer to plans attributable to HIPAA's statutory nondiscrimination provisions probably amounts to a small fraction of 1 percent of total expenditures by these plans.

The Departments believe that the benefits of the regulation outweigh its costs.

A fuller discussion of the Departments assessment of the costs and benefits of this regulation is provided below.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires that the agency present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rule making describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations, and governmental jurisdictions.

Because these rules are being issued as interim final rules and not as a notice of proposed rule making, the RFA does not apply and the Departments are not required to either certify that the rule will not have a significant impact on a substantial number of small businesses or conduct a regulatory flexibility analysis. The Departments nonetheless crafted this regulation in careful consideration of its effects on small entities, and have conducted an analysis of the likely impact of the rules on small entities.

For purposes of this discussion, the Departments consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans which cover fewer than 100 participants. The Departments believe that assessing the impact of this interim final rule on small plans is an appropriate substitute for evaluating the effect on small entities as that term is defined in the RFA.

Small plans in particular will benefit from the regulations' provisions that affirm and clarify the flexibility available to plans under HIPAA's nondiscrimination requirements. Consideration of small plans' needs and circumstances played an important part in the development of these provisions. These provisions are discussed in more detail below.

The Departments estimate that plans with 100 or fewer participants will incur costs of $4 million on aggregate to amend their provisions to comply with the regulation and revise their materials accordingly. These costs generally will fall directly to issuers who supply small group insurance products and stop-loss insurers who provide services to small self-insured plans, who will spread those costs across the much larger number of small plans that buy them. These same small plans will incur costs of $10 million to prepare and distribute notices of enrollment opportunities as required by the regulation, the Departments estimate. The total economic cost to small plans to comply with this regulation is estimated to be $14 million. This is a one-time cost distinguishable from the transfer that will result from the self-implementing requirements of HIPAA's nondiscrimination provisions and the discretion exercised by the Departments in this regulation.

Such a transfer occurs when resources are redistributed without any direct change in aggregate social welfare. In this instance, the premium and claims cost incurred by group health plans to provide coverage under HIPAA's statutory nondiscrimination provisions to individuals previously denied coverage or offered restricted coverage based on health factors are offset by the commensurate or greater benefits realized by the newly eligible participants on whose behalf the premiums or claims are paid. The Departments note that transfers to small plans attributable to HIPAA's statutory nondiscrimination provisions may amount to approximately $110 million. The regulation clarifies at the margin exactly what practices are permitted or prohibited by these provisions, and may have the effect of slightly increasing the amount of this transfer. The Departments note that this transfer is the direct reflection of the intent and beneficial effect of HIPAA's nondiscrimination provisions: increasing access to affordable group health plan coverage for individuals with health problems. They also note that even the full transfer to small plans attributable to HIPAA's statutory nondiscrimination provisions amounts to a small fraction of total expenditures by these plans.

Paperwork Reduction Act—Department of Labor and Department of the Treasury

1. Department of Labor

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95), 44 U.S.C. 3506(c)(2)(A). This helps to ensure that requested data can be provided in the desired format,

reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Pension and Welfare Benefits Administration (PWBA) is soliciting comments concerning the proposed information collection request (ICR) included in the Interim Final Rules for Nondiscrimination in Health Coverage in the Group Market.

The Department has submitted this ICR using emergency review procedures to the Office of Management and Budget (OMB) for its review and clearance in accordance with PRA 95. OMB approval has been requested by March 9, 2001. The Department and OMB are particularly interested in comments that:

- Evaluate whether the proposed collection of information is 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 the proposed collection of information, 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 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, *e.g.,* permitting electronic submission of the responses.

Comments on the collection of information should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington DC 20503; Attention: Desk Officer for the Pension and Welfare Benefits Administration. Although comments may be submitted through March 9, 2001, OMB requests that comments be received within February 7, 2001 of the publication of the Interim Final Rule to ensure their consideration in OMB's review of the request for emergency approval. All comments will be shared among the Departments.

Requests for copies of the ICR may be addressed to: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, NW, Room N–5647, Washington, DC, 20210. Telephone: (202) 219–4782; Fax: (202) 219–4745 (these are not toll-free numbers).

2. Department of the Treasury

The collection of information is in 26 CFR 54.9802–1T(*i*)(3)(ii) and (iii). This information is required to be provided so that participants who have been denied group health plan coverage based on a health status factor may be made aware of the opportunity to enroll in the plan. The likely respondents are business or other for-profit institutions, non-profit institutions, small businesses or organizations, and Taft-Hartley trusts. Responses to this collection of information are mandatory for affected group health plans.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC, 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224. Comments on the collection of information should be received by February 7, 2001. In light of the request for OMB clearance by March 9, 2001, the early submission of comments is encouraged to ensure their consideration. Comments are specifically requested concerning:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;
- How to enhance the quality, utility, and clarity of the information to be collected;
- How to minimize the burden of complying with the proposed collection of information, including the application of automated collection techniques or other forms of information technology; and
- Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

3. Description of Collection of Information

29 CFR 2590.702(*i*)(3)(ii) and (iii) and 26 CFR 54.9802–1T(*i*)(3)(ii) and (iii) of these interim rules include information collection requests. Paragraphs (*i*)(3)(ii) and (iii) describe the requirement that individuals previously denied coverage under a group health plan be provided with an opportunity to enroll in the plan, and a notice concerning this opportunity. Pursuant to paragraph (*i*)(3)(ii), where coverage denials were not based on a good faith interpretation of section 702 of the ERISA and section 9802 of the Code, notices of the opportunity for individuals previously denied coverage to enroll are required to be provided within 60 days of publication of this interim final rule. Where coverage was denied based on a good faith interpretation of section 702 of ERISA and section 9802 of the Code, the plan or issuer must provide notice of the opportunity to enroll that continues for at least 30 days, with coverage effective no later than July 1, 2001.

The method of estimating the hour and cost burdens of the information collection request is described in the section of this preamble appearing below entitled *Costs and Benefits of the Regulation.* Generally, the Departments have conservatively estimated that all group health plans that excluded individuals on the basis of health status factors prior to HIPAA's enactment will provide a notice of the opportunity to enroll to all participants. The total burden of providing notices to participants of private employers is divided equally between the Departments of Labor and Treasury.

Paragraph (h), *No effect on other laws,* is not considered to include an information collection request because the provision makes no substantive or material change to the Department of Labor's existing information collection request for the Summary Plan Description and Summary of Material Modifications currently approved under OMB control number 1210–0039.

Type of Review: New.

Agency: Pension and Welfare Benefits Administration, Department of Labor; U.S. Department of the Treasury, Internal Revenue Service.

Title: Notice of Opportunity To Enroll.

OMB Number: 1210–0NEW; 1545–0NEW.

Affected Public: Individuals or households; Business or other for-profit institutions; Not-for-profit institutions.

Total Respondents: 120,000.

Frequency of Response: One time.

Total Responses: 2.0 million.

Estimated Burden Hours: 5,950 (Pension and Welfare Benefits Administration); 5,950 (Internal Revenue Service).

Estimated Annual Costs (Operating and Maintenance): $5.1 million

(Pension and Welfare Benefits Administration); $5.1 million (Internal Revenue Service).

Estimated Total Annual Costs: $5.1 million (Pension and Welfare Benefits Administration); $5.1 million (Internal Revenue Service).

Comments submitted in response to the information collection provisions of these Interim Final, final, and temporary rules will be shared among the Departments and summarized and/or included in the request for continuing OMB approval of the information collection request; they will also become a matter of public record.

Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are, however, requesting an emergency review of this interim final rule with comment period. In compliance with section 3506(c)(2)(A) of the PRA, we are submitting to OMB the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320, to ensure compliance with section 2702 of the PHS Act. This section generally prohibits group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries. We cannot reasonably comply with normal clearance procedures because public harm is likely to result if the agency cannot enforce the requirements of this section 2702 of the PHS Act in order to ensure that individual participants or beneficiaries are not subject to unfair discrimination.

HCFA is requesting OMB review and approval of this collection 60 working days after the publication of this rule, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 30 working days after the publication of this rule.

During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

We are soliciting public comment on each of the issues for the provisions summarized below that contain information collection requirements:

Section 146.121 Prohibiting Discrimination Against Participants and Beneficiaries Based on a Health Factor.

(h) *No effect on other laws.* Although this section generally does not impose new disclosure obligations on plans and issuers, this paragraph (h) states that this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation. Therefore, plan documents (including, for example, group health insurance policies and certificates of insurance) must be amended if they do not accurately reflect the requirements set forth in this section, by the applicability date of this section.

The revisions to the plan documents are intended to eliminate provisions that do not comply with the HIPAA nondiscrimination statute and regulations. In particular, it is anticipated that changes will be required to the majority of actively-at-work provisions and nonconfinement clauses found in plan documents. The modifications are to be made by the applicability date of the regulation and the requirements do not impose any on-going burden. The revisions are anticipated to take 100 hours for state governmental plans and 4,900 hours for local governmental plans. The changes are expected to involve one hour of an attorney's time at a $72 hourly rate. The corresponding plan amendment cost to be performed by service providers who are acting on behalf of the plans, is $32,000 for State governmental plans and $1,311,000 for local governmental plans.

(i) *Special transitional rule for self-funded non-Federal governmental plans exempted under 45 CFR 146.180.* Paragraph (4)(i) requires that if coverage has been denied to any individual because the sponsor of a self-funded non-Federal governmental plan has elected under § 146.180 of this part to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan must: notify the individual that the plan will be coming into compliance with the requirements of this section; afford the individual an opportunity that continues for at least 30 days, specify the effective date of compliance; and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a matter of administrative convenience; the notice may be disseminated to all employees).

The regulation clarifies that self-funded non-Federal governmental plans are required to give individuals who were previously discriminated against an opportunity to enroll, including notice of an opportunity to enroll. The development of the number of plans that are required to notify individuals were conservatively arrived at by assuming that all plans which have excluded individuals must notify all individuals who are eligible to participate in the plan. Development of the transitional notices are estimated to take 0 hours for State governmental plans and 200 hours for local governmental plans. The corresponding burden for work performed by service providers is anticipated to be $1,000 for State governmental plans and $535,000 for local governmental plans. The Department estimates that the burden to distribute transitional notices will require State governmental plans 800 hours and 1,400 hours for local governmental plans. The corresponding distribution burden performed by service providers is $72,000 for State governmental plans and $158,000 for local governmental plans.

The above costs will be reduced to the extent that State and local governmental plans have elected to opt out of the HIPAA requirements. As of the date of publishing, approximately 600 plans have opted out of the HIPAA statutory and regulatory requirements.

We have submitted a copy of this rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record

keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–2022,

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Allison Herron Eydt, HCFA–2022.

Small Business Regulatory Enforcement Fairness Act

This interim final rule is subject to the provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and is being transmitted to Congress and the Comptroller General for review. The interim final rule, is a ''major rule,'' as that term is defined in 5 U.S.C. 804, because it is likely to result in an annual effect on the economy of $100 million or more. As such, this interim final rule is being transmitted to Congress and the Comptroller General for review.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, this interim final rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor does it include mandates which may impose an annual burden of $100 million or more on the private sector.

Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these interim final regulations do not have federalism implications, because they do not have substantial direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. This is largely because, with respect to health insurance issuers, the vast majority of States have enacted laws which meet or exceed the federal standards in HIPAA prohibiting discrimination based on health factors. Therefore, the regulations are not likely to require substantial additional oversight of States by the Department of Health and Human Services.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) preserving the applicability of State laws establishing requirements for issuers of group health insurance coverage, except to the extent that these requirements prevent the application of the portability, access, and renewability requirements of HIPAA. The nondiscrimination provisions that are the subject of this rulemaking are included among those requirements.

In enacting these new preemption provisions, Congress indicated its intent to establish a preemption of State insurance requirements only to the extent that those requirements prevent the application of the basic protections set forth in HIPAA. HIPAA's Conference Report states that the conferees intended the narrowest preemption of State laws with regard to health insurance issuers. H.R. Conf. Rep. No. 736, 104th Cong. 2d Session 205 (1996). Consequently, under the statute and the Conference Report, State insurance laws that are more stringent than the federal requirements are unlikely to ''prevent the application of'' the HIPAA nondiscrimination provisions.

Accordingly, States are given significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law. In many cases, the federal law imposes minimum requirements which States are free to exceed. Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 and these regulations do not reduce the discretion given to the States by the statute. It is the Departments' understanding that the vast majority of States have in fact implemented provisions which meet or exceed the minimum requirements of the HIPAA non-discrimination provisions.

HIPAA provides that the States may enforce the provisions of HIPAA as they pertain to issuers, but that the Secretary of Health and Human Services must enforce any provisions that a State fails to substantially enforce. When exercising its responsibility to enforce the provisions of HIPAA, HCFA works cooperatively with the States for the purpose of addressing State concerns and avoiding conflicts with the exercise of State authority.[14] HCFA has developed procedures to implement its enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA's requirements in the first instance. HCFA's procedures address the handling of reports that States may not be enforcing HIPAA's requirements, and the mechanism for allocating enforcement responsibility between the States and HCFA. To date, HCFA has had occasion to enforce the HIPAA non-discrimination provisions in only two States.

Although the Departments conclude that these interim final rules do not have federalism implications, in keeping with the spirit of the Executive Order that agencies closely examine any policies that may have federalism implications or limit the policy making discretion of the States, the Department of Labor and HCFA have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials.

For example, the Departments were aware that some States commented on the way the federal provisions should be interpreted. Therefore, the Departments have sought and received input from State insurance regulators and the National Association of Insurance Commissioners (NAIC). The NAIC is a non-profit corporation established by the insurance commissioners of the 50 States, the District of Columbia, and the four U.S. territories, that among other

[14] This authority applies to insurance issued with respect to group health plans generally, including plans covering employees of church organizations. Thus, this discussion of federalism applies to all group health insurance coverage that is subject to the PHS Act, including those church plans that provide coverage through a health insurance issuer (but not to church plans that do not provide coverage through a health insurance issuer). For additional information relating to the application of these nondiscrimination rules to church plans, see the preamble to regulations being proposed elsewhere in this issue of the **Federal Register** regarding section 9802(c) of the Code relating to church plans.

things provides a forum for the development of uniform policy when uniformity is appropriate. Its members meet, discuss, and offer solutions to mutual problems. The NAIC sponsors quarterly meetings to provide a forum for the exchange of ideas, and in-depth consideration of insurance issues by regulators, industry representatives, and consumers. HCFA and Department of Labor staff have attended the quarterly meetings consistently to listen to the concerns of the State Insurance Departments regarding HIPAA issues, including the nondiscrimination provisions. In addition to the general discussions, committee meetings and task groups, the NAIC sponsors the following two standing HIPAA meetings for members during the quarterly conferences:

- HCFA/DOL Meeting on HIPAA Issues (This meeting provides HCFA and Labor the opportunity to provide updates on regulations, bulletins, enforcement actions and outreach efforts regarding HIPAA.)
- The NAIC/HCFA Liaison Meeting (This meeting provides HCFA and the NAIC the opportunity to discuss HIPAA and other health care programs.)

In addition, in developing these interim final regulations, the Departments consulted with the NAIC and requested their assistance to obtain information from the State Insurance Departments. Specifically, we sought and received their input on certain insurance rating practices and late enrollment issues.

The Departments employed the States' insights on insurance rating practices in developing the provisions prohibiting ''list-billing,'' and their experience with late enrollment in crafting the regulatory provision clarifying the relationship between the nondiscrimination provisions and late enrollment. Specifically, the regulations clarify that while late enrollment, if offered by a plan, must be available to all similarly situated individuals regardless of any health factor, an individual's status as a late enrollee is not itself within the scope of any health factor.

The Departments also cooperate with the States in several ongoing outreach initiatives, through which information on HIPAA is shared among federal regulators, State regulators, and the regulated community. In particular, the Department of Labor has established a Health Benefits Education Campaign with more than 70 partners, including HCFA, NAIC and many business and consumer groups. HCFA has sponsored four conferences with the States—the Consumer Outreach and Advocacy conferences in March 1999 and June 2000, the Implementation and Enforcement of HIPAA National State-Federal Conferences in August 1999 and 2000. Furthermore, both the Department of Labor and HCFA websites offer links to important State websites and other resources, facilitating coordination between the State and federal regulators and the regulated community.

In conclusion, throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA, the Departments have attempted to balance the States' interests in regulating health insurance issues, and Congress's intent to provide uniform minimum protections to consumers in every State.

Unified Analysis of Costs and Benefits

1. Introduction

HIPAA's nondiscrimination provisions generally prohibit group health plans and group health plan issuers from discriminating against individuals on the basis of health status factors. The primary effect and intent of the provision is to increase access to affordable group health coverage for individuals with health problems. This effect, and the economic costs, benefits, and transfers attendant to it, generally flow directly from the HIPAA's statutory provisions, which are largely self-implementing. However, the statute alone leaves room for varying interpretations of exactly which practices are prohibited or permitted at the margin. This regulation draws on the Departments' authority to clarify and interpret HIPAA's statutory nondiscrimination provisions in order to secure the protections intended by Congress for plan participants and beneficiaries. The Departments crafted it to satisfy this mandate in as economically efficient a manner as possible, and believe that the economic benefits of the regulation outweigh its costs. The analysis underlying this conclusion takes into account both the effect of the statute and the impact of the discretion exercised in the regulation.

The nondiscrimination provisions of the HIPAA statute and of this regulation generally apply to both group health plans and to issuers of group health plan policies. Economic theory predicts that issuers will pass their costs of compliance back to plans, and that plans may pass some or all of issuers' and their own costs of compliance to participants. This analysis is carried out in light of this prediction.

2. Costs and Benefits of HIPAA's Statutory Nondiscrimination Provisions

As noted above, HIPAA's statutory nondiscrimination provisions are largely self-implementing even in the absence of interpretive guidance. It is the Departments' policy where practicable to evaluate such impacts separately from the impact of discretion exercised in regulation. The Departments provide qualitative assessments of the nature of the costs, benefits, and transfers that are expected to derive from statutory provisions, and provide summaries of any credible, empirical estimates of these effects that are available.

To the Departments' knowledge, there is no publicly available work that quantifies the magnitude or presents the nature of these benefits, costs, and transfers. In its initial scoring of the statute, the Congressional Budget Office did not separately quantify the costs of the nondiscrimination provisions. Therefore, this analysis considers the nature of anticipated costs, benefits, and transfers, and offers a basis for estimating separately the impacts of the statute and regulatory discretion, but does not present a detailed description of any other quantitative analysis of the statute's impact.

HIPAA's statutory nondiscrimination provisions entail new economic costs and benefits, as well as transfers of health care costs among plan sponsors and participants.

The primary statutory economic benefits associated with the HIPAA nondiscrimination provisions derive from increased access to affordable group health plan coverage for individuals with certain health status-related factors. Expanding access benefits both newly covered individuals and society at large. Individuals without health insurance are less likely to get preventive care and less likely to have a regular source of care.[15] A lack of health insurance generally increases the likelihood that needed medical treatment will be forgone or delayed. Forgoing or delaying care increases the risk of adverse health outcomes. These adverse outcomes in turn spawn higher medical costs which are often shifted to public funding sources (and therefore to taxpayers) or to other payers. They also erode productivity and the quality of life. Improved access to affordable group health coverage for individuals with health problems under HIPAA's

[15] Kaiser Family Foundation and the NewsHour, ''Newshour/Kaiser Spotlights Misconceptions About the Medically Uninsured: Survey Examines Difficulties Faced by Those Without Health Coverage,'' News Release, May 16, 2000.

nondiscrimination provisions will lead to more insurance coverage, timelier and fuller medical care, better health outcomes, and improved productivity and quality of life. This is especially true for the individuals most affected by HIPAA's nondiscrimination provisions—those with adverse health conditions. Denied insurance, individuals in poorer health are more likely to suffer economic hardship, to forgo badly needed care for financial reasons, and to suffer adverse health outcomes as a result. For them, gaining insurance is more likely to mean gaining economic security, receiving timely, quality care, and living healthier, more productive lives.

Plans and issuers will incur economic costs as a result of the law. These are generally limited to administrative costs, such as those incurred to change plan design and pricing structures and update plan materials.

The premiums and claims costs incurred by group health plans to provide coverage to individuals who were previously denied coverage or offered restricted coverage based on health factors are offset by the commensurate or greater benefits realized by the newly eligible participants on whose behalf the premiums or claims are paid. As such, these premiums and claims costs are properly characterized as transfers rather than as new economic costs. These transfers shift the burden of health care costs from one party to another without any direct change in aggregate social welfare. For example, as individuals' insurance status changes from insured through an individual policy to insured through an employment based group health plan, health care costs are transferred from these individuals to their employers. Similarly, as individuals' insurance status changes from uninsured to insured through a group health plan, health care costs are transferred from the individuals and public funding sources to employers.

The HIPAA nondiscrimination statutory transfer is likely to be substantial. Annual per-participant group health plan costs average more than $4,000,[16] and it is likely that average costs would be higher for individuals who had faced discrimination due to health status factors. Prior to HIPAA's enactment approximately 106,000 employees were denied employment based coverage because of health factors.[17] A simple assessment suggests that the total cost of coverage for such employees could exceed $400 million. However, this potential statutory transfer is small relative to the overall cost of employment-based health coverage. Group health plans will spend about $431 billion this year to cover approximately 77 million participants and their dependents. Transfers under HIPAA's nondiscrimination provision will represent a very small fraction of one percent of total group health plan expenditures.

3. Costs and Benefits of the Regulation

Prohibiting Discrimination—Many of the provisions of this regulation serve to specify more precisely than the statute alone exactly what practices are prohibited by HIPAA as unlawful discrimination in eligibility or employee premium among similarly situated employees. For example, under the regulation eligibility generally may not be restricted based on an individuals' participation in risky activities, confinement to an institution or absence from work on enrollment day due to illness, or status as a late enrollee. The regulation provides that various plan features including waiting periods and eligibility for certain benefits constitute rules for eligibility which may not vary across similarly situated employees based on health status factors. It provides that individuals who were previously denied eligibility based on health status factors (or who failed to enroll in anticipation of such denial) must be given an opportunity to enroll. It provides that plans may not reclassify employees based on health status factors in order to create separate groups of similarly situated employees among which discrimination would be permitted.

All of these provisions have the effect of clarifying and ensuring certain participants' right to freedom from discrimination in eligibility and premium amounts, thereby securing their access to affordable group health plan coverage. The costs and benefits attributable to these provisions resemble those attendant to HIPAA's statutory nondiscrimination provisions. Securing participants' access to affordable group coverage provides economic benefits by reducing uninsurance and thereby improving health outcomes. It entails transfers of costs from the employees whose rights are secured (and/or from other parties who would otherwise pay for their health care) to plan sponsors (or to other plan participants if sponsors pass those costs back evenly to them). And it imposes economic costs in the form of administrative burdens to design and implement necessary plan amendments.

The Departments lack any basis on which to distinguish these benefits, costs, and transfers from those of the statute itself. It is unclear how many plans might be engaging in the discriminatory practices targeted for prohibition by these regulatory provisions. Because these provisions operate largely at the margin of the statutory requirements, it is likely that the effects of these provisions will be far smaller than the similar statutory effects. The Departments are confident, however, that by securing employees' access to affordable coverage at the margin, the regulation, like the statute, will yield benefits in excess of costs.

Clarifying Requirements—Additional economic benefits derive directly from the improved clarity provided by the regulation. The regulation provides clarity through both its provisions and its examples of how those provisions apply in various circumstances. By clarifying employees' rights and plan sponsors' obligations under HIPAA's nondiscrimination provisions, the regulation will reduce uncertainty and costly disputes over these rights and obligations. It will promote employers' and employees' common understanding of the value of group health plan benefits and confidence in the security and predictability of those benefits, thereby improving labor market efficiency and fostering the establishment and continuation of group health plans by employers.[18]

[16] Gabel, Jon R. Job-based Health Insurance, 1977–1998: The Accidental System Under Scrutiny. *Health Affairs.* November/December 1999. Volume 18, Number 6.

[17] February 1997 Current Population Survey, Contingent Worker Supplement.

[18] The voluntary nature of the employment-based health benefit system in conjunction with the open and dynamic character of labor markets make explicit as well as implicit negotiations on compensation a key determinant of the prevalence of employee benefits coverage. It is likely that 80% to 100% of the cost of employee benefits is borne by workers through reduced wages (see for example Jonathan Gruber and Alan B. Krueger, ''The Incidence of Mandated Employer-Provided Insurance: Lessons from Workers Compensation Insurance,'' Tax Policy and Economy (1991); Jonathan Gruber, ''The Incidence of Mandated Maternity Benefits,'' American Economic Review, Vol. 84 (June 1994), pp. 622–641; Lawrence H. Summers, ''Some Simple Economics of Mandated Benefits,'' American Economic Review, Vol. 79, No. 2 (May 1989); Louise Sheiner, ''Health Care Costs, Wages, and Aging,'' Federal Reserve Board of Governors working paper, April 1999; and Edward Montgomery, Kathryn Shaw, and Mary Ellen Benedict, ''Pensions and Wages: An Hedonic Price Theory Approach,'' International Economic Review, Vol. 33 No. 1, Feb. 1992.) The prevalence of benefits is therefore largely dependent on the efficacy of this exchange. If workers perceive that there is the potential for inappropriate denial of benefits they will discount their value to adjust for this risk. This discount drives a wedge in the compensation

Amending Plans—The regulation is expected to entail some new economic costs, in the form of two new administrative burdens, which are distinguishable from those attributable to the statute. First, it is likely that some of the regulation's nondiscrimination provisions will effectively require some plans to amend their terms and revise plan materials. Second, as noted above, the regulation requires that individuals who were previously denied eligibility based on health status factors (or who failed to enroll in anticipation of such denial) must be given an opportunity to enroll. It also requires that plans notify such individuals of their right enroll. Providing notices under these requirements will entail new administrative costs.

Plans that, prior to HIPAA's effective date, included provisions since prohibited by HIPAA's nondiscrimination requirements, were effectively required by HIPAA to implement conforming amendments and to revise plan materials accordingly. The costs associated with these actions generally are attributable to the HIPAA statute and not to this regulation. However, it is likely that some of the regulation's nondiscrimination provisions will effectively require some plans to amend their terms and revise their materials. For example, the Departments understand that plans commonly require employees to be actively at work on a designated enrollment day in order to qualify for enrollment. It is possible that some plans failed to interpret HIPAA's statutory provisions to prohibit this practice. Such plans will need to amend their terms and materials to provide that employees will not be denied enrollment solely because they were absent due to a health status factor. Such plans will incur administrative costs.

The Departments have no basis for estimating how many plans might need to implement amendments beyond those implemented in response to the HIPAA's statutory nondiscrimination provisions in order to comply with the regulation's corresponding provisions. They adopted conservative assumptions in order to develop an upper bound estimate of the cost to amend plans and materials to conform with the regulation. They assumed that all plans will require at least some amendment to conform with this regulation.

A large majority of fully insured plans do not have unique eligibility and employee premium provisions but instead choose from a relatively small menu of standardized products offered by issuers. The Departments accordingly assumed that issuers will amend their standardized group insurance products, passing the associated cost back to the plans that buy them. They estimate that a total of approximately 33,000 group insurance products will be so amended, and that the cost of these amendments will be spread across a universe of approximately 2.6 million fully insured plans. The Departments assumed that small self-insured plans (which generally fall outside state regulation of insurance products) choose from a much larger menu of products and that large self-insured plans each have unique eligibility rules will need to be amended independently. This implies a total of approximately 76,000 self-insured plan configurations requiring amendment.

Assuming that each affected group insurance product and self-insured plan configuration would require 1 hour of professional time billed at $72 per hour to design and implement amendments, the aggregate cost to amend plans would be $8 million.

Separate from the cost to design and implement plan amendments is the cost to revise plan materials to reflect the amendments. The Departments note that the cost to revise plan materials can generally be attributed to legal requirements other than the HIPAA statute or this regulation. It is the policy of the Department of Labor to attribute the cost of revising private-sector group health plan materials to its regulation implementing ERISA's Summary Plan Description requirements. Various state laws compel issuers to provide accurate materials, and the Departments believe that State and local governmental plan sponsors and private plan sponsors routinely update plan materials as a matter of either law or compensation and employment policy.

Notifying Employees of Enrollment Opportunities—In estimating the costs associated with the notification requirements, the Departments separately considered the cost of preparing notices and the cost of distributing them.

Based on a 1993 Robert Wood Johnson Foundation survey of employers, the Departments estimate that 128,000 group health plans excluded individuals on the basis of health status factors prior to HIPAA's enactment and will therefore be required by the regulation to prepare and distribute notices. The Departments assumed that preparing the notice will require one hour of time billed at a $72 hourly rate. The cost to develop notices is therefore estimated to be $9 million.

The Departments assumed that plans will distribute notices to all individuals who are eligible for coverage under the plan. It might be necessary to notify individuals who are currently enrolled because such individuals may have dependents for whom eligibility was denied based on a health status factor or may have failed to enroll dependents because they expected that eligibility would be so denied for them. This assumption probably results in an overestimate of the true cost. Some affected plans may already have notified affected individuals of their right to enroll under HIPAA. Others may have historical records of plan enrollment that are sufficiently detailed to allow for the notification of only specific individuals. Based on the 1997 Robert Wood Johnson Foundation survey, the Departments estimate that a total of 2.3 million employees are eligible for coverage under the 128,000 plans that are required to provide notices. The Departments assumed that distributing each notice costs $0.37 for mailing and materials plus 2 minutes of photocopying and mailing billed at a $15 per hour clerical rate for a total per-notice distribution cost of $0.87. The cost to distribute notices is therefore estimated to be $2 million.

The estimated combined cost to prepare and distribute notices therefore amounts to $11 million. The Departments note that this is a one-time cost which will be incurred concurrent with the regulation's applicability date.

The Department's note that the provision of notices will benefit employees who newly learn of opportunities to enroll themselves or their dependents. The result will be fuller realization of HIPAA's intent and employees' associated rights, as well as improved access to affordable group coverage and reduced rates of uninsurance for affected employees.

4. Summary of Cost Estimates

The cost estimates presented here are compiled in the table below. Upper bound cost estimates attributable to the regulation include $8 million to amend plans and revise documents and $11 million to prepare and distribute notices of enrollment opportunities, or a total of $19 million.

negotiation, limiting its efficiency. With workers unwilling to bear the full cost of the benefit, fewer benefits will be provided. The extent to which workers perceive a federal regulation supported by enforcement authority to improve the security and quality of benefits, the differential between the employers costs and workers willingness to accept wage offsets is minimized.

Source of cost	$MM	Explanatory notes
Amending plans and revising materials	$8	Upper bound of new economic cost incurred as plans are amended to comply with the regulation. One-time cost.
Notifying employees of enrollment opportunities	$11	Upper bound of new economic cost to prepare and distribute notices. One-time cost.
Prohibiting discrimination	>$400	Transfer attributable to HIPAA's statutory nondiscriminatory provisions. Transfers attributable to the regulation were not estimated but are expected to be a very small fraction of this amount. Ongoing annual level.

5. Assessment of Likelihood of Adverse Secondary Effects

The Departments considered whether employers might reduce or eliminate health insurance benefits for all employees as a result of this regulation. They believe that this is highly unlikely because the regulation affirms and clarifies plan sponsors' flexibility and because its costs will be very small relative to group health plan expenditures.

The regulation affirms plan sponsors' flexibility to design plans and control plan costs in many ways. It affirms and clarifies plans' flexibility under HIPAA to exclude from coverage or limit coverage for certain conditions or services, to require employees to perform services before coverage becomes effective, and to provide different benefits or charge different premiums for employees in different bona fide employment classes. It also clarifies that more favorable treatment of individuals with adverse health factors is permitted, thereby allowing employers to assist employees and their families dealing with disabilities, medical conditions, or other health factors by extending coverage or lowering premiums.

Both the transfer of health insurance costs and the administrative costs generated by this regulation will be very small relative to total group health plan expenditures. The $19 million economic cost estimate attributed to this regulation amounts to a tiny fraction of one percent of the $431 billion that group health plans will spend this year. Even the more than $400 million transfer of cost attributed to HIPAA's statutory nondiscrimination provisions amount to a very small fraction of one percent of that spending. Plan sponsors wishing to do so generally can pass these costs back to participants with small, across the board changes to employee premiums or benefits.

Statutory Authority

The Department of the Treasury final and temporary rules are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code (26 U.S.C. 7805, 9833).

The Department of Labor interim final rule is adopted pursuant to the authority contained in sections 107, 209, 505, 701–703, 711–713, and 731–734 of ERISA (29 U.S.C. 1027, 1059, 1135, 1171–1173, 1181, 1182, and 1191–1194), as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436), section 101(g)(4) of HIPAA, and Secretary of Labor's Order No. 1–87, 52 FR 13139, April 21, 1987.

The Department of HHS interim final rule is adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Employee benefit plans, Employee Retirement Income Security Act, Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Adoption of Amendments to the Regulations

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 54.9802–1T is removed.

Par. 3. Section 54.9802–1 is added to read as follows:

§ 54.9802–1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) *Health factors.* (1) The term *health factor* means, in relation to an individual, any of the following health status-related factors:

(i) Health status;

(ii) Medical condition (including both physical and mental illnesses);

(iii) Claims experience;

(iv) Receipt of health care;

(v) Medical history;

(vi) Genetic information;

(vii) Evidence of insurability; or

(viii) Disability.

(2) Evidence of insurability includes—

(i) Conditions arising out of acts of domestic violence; and

(ii) [Reserved] For further guidance, see § 54.9802–1T(a)(2)(ii).

(b) *Prohibited discrimination in rules for eligibility*—(1) *In general*—(i) A group health plan may not establish any rule for eligibility (including continued eligibility) of any individual to enroll for benefits under the terms of the plan that discriminates based on any health factor that relates to that individual or a dependent of that individual. This rule is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (b)(3) of this section (allowing plans to impose certain preexisting condition exclusions), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to bona fide wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

(ii) [Reserved] For further guidance, see § 54.9802–1T(b)(1)(ii).

(iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, employees who do not enroll within the first 30 days cannot enroll later unless they pass a physical examination.

(ii) *Conclusion.* In this *Example 1*, the requirement to pass a physical examination in order to enroll in the plan is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 2. [Reserved]

(2) *Application to benefits*—(i) *General rule*—(A) Under this section, a group health plan is not required to provide coverage for any particular benefit to any group of similarly situated individuals.

(B) [Reserved] For further guidance, see § 54.9802–1T(b)(2)(i)(B).

(C) [Reserved] For further guidance, see § 54.9802–1T(b)(2)(i)(C).

(D) [Reserved] For further guidance, see § 54.9802–1T(b)(2)(i)(D).

(ii) *Cost-sharing mechanisms and wellness programs.* A group health plan with a cost-sharing mechanism (such as a deductible, copayment, or coinsurance) that requires a higher payment from an individual, based on a health factor of that individual or a dependent of that individual, than for a similarly situated individual under the plan (and thus does not apply uniformly to all similarly situated individuals) does not violate the requirements of this paragraph (b)(2) if the payment differential is based on whether an individual has complied with the requirements of a bona fide wellness program.

(iii) *Specific rule relating to source-of-injury exclusions.* [Reserved] For further guidance, see § 54.9802–1T(b)(2)(iii).

(3) *Relationship to section 9801(a), (b), and (d).* [Reserved] For further guidance, see § 54.9802–1T(b)(3).

(c) *Prohibited discrimination in premiums or contributions*—(1) *In general*—(i) A group health plan may not require an individual, as a condition of enrollment or continued enrollment under the plan, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual (described in paragraph (d) of this section) enrolled in the plan based on any health factor that relates to the individual or a dependent of the individual.

(ii) [Reserved] For further guidance, see § 54.9802–1T(c)(1)(ii).

(2) *Rules relating to premium rates*—(i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan.

(ii) *List billing based on a health factor prohibited.* [Reserved] For further guidance, see § 54.9802–1T(c)(2)(ii).

(3) *Exception for bona fide wellness programs.* Notwithstanding paragraphs (c)(1) and (2) of this section, a plan may establish a premium or contribution differential based on whether an individual has complied with the requirements of a bona fide wellness program.

(d) *Similarly situated individuals.* [Reserved] For further guidance, see § 54.9802–1T(d).

(e) *Nonconfinement and actively-at-work provisions.* [Reserved] For further guidance, see § 54.9802–1T(e).

(f) *Bona fide wellness programs.* [Reserved]

(g) *Benign discrimination permitted.* [Reserved] For further guidance, see § 54.9802–1T(g).

(h) *No effect on other laws.* [Reserved] For further guidance, see § 54.9802–1T(h).

(i) *Effective dates*—(1) Final rules apply March 9, 2001. This section applies March 9, 2001.

(2) *Cross-reference to temporary rules applicable for plan years beginning on or after July 1, 2001.* See § 54.9802–1T(i)(2), which makes the rules of that section applicable for plan years beginning on or after July 1, 2001.

(3) *Cross-reference to temporary transitional rules for individuals previously denied coverage based on a health factor.* See § 54.9802–1T(i)(3) for transitional rules that apply with respect to individuals previously denied coverage under a group health plan based on a health factor.

Par. 4. Section 54.9802–1T is added to read as follows:

§ 54.9802–1T Prohibiting discrimination against participants and beneficiaries based on a health factor (temporary).

(a) *Health factors.* (1) [Reserved] For further guidance, see § 54.9802–1(a).

(2) Evidence of insurability includes—

(i) [Reserved] For further guidance, see § 54.9802–1(a)(2)(i).

(ii) Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities.

(3) The decision whether health coverage is elected for an individual (including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor. (However, under section 9801(f) a plan must treat special enrollees the same as similarly situated individuals who are enrolled when first eligible.)

(b) *Prohibited discrimination in rules for eligibility*—(1) *In general*—(i) [Reserved] For further guidance, see § 54.9802–1(b)(1)(i).

(ii) For purposes of this section, rules for eligibility include, but are not limited to, rules relating to—

(A) Enrollment;

(B) The effective date of coverage;

(C) Waiting (or affiliation) periods;

(D) Late and special enrollment;

(E) Eligibility for benefit packages (including rules for individuals to change their selection among benefit packages);

(F) Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles), as described in paragraphs (b) (2) and (3) of this section;

(G) Continued eligibility; and

(H) Terminating coverage (including disenrollment) of any individual under the plan.

(iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. [Reserved] For further guidance, see § 54.9802–1(b)(iii). *Example 1.*

Example 2. (i) *Facts.* Under an employer's group health plan, employees who enroll during the first 30 days of employment (and during special enrollment periods) may choose between two benefit packages: an indemnity option and an HMO option. However, employees who enroll during late enrollment are permitted to enroll only in the HMO option and only if they provide evidence of good health.

(ii) *Conclusion.* In this *Example 2,* the requirement to provide evidence of good health in order to be eligible for late enrollment in the HMO option is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1). However, if the plan did not require evidence of good health but limited late enrollees to the HMO option, the plan's rules for eligibility would not discriminate based on any health factor, and thus would not violate this paragraph (b)(1), because the time an individual chooses to enroll is not, itself, within the scope of any health factor.

Example 3. (i) *Facts.* Under an employer's group health plan, all employees generally may enroll within the first 30 days of employment. However, individuals who participate in certain recreational activities, including motorcycling, are excluded from coverage.

(ii) *Conclusion.* In this *Example 3,* excluding from the plan individuals who participate in recreational activities, such as motorcycling, is a rule for eligibility that discriminates based on one more health factors and thus violates this paragraph (b)(1).

Example 4. (i) *Facts.* A group health plan applies for a group health policy offered by

an issuer. As part of the application, the issuer receives health information about individuals to be covered under the plan. Individual *A* is an employee of the employer maintaining the plan. *A* and *A*'s dependents have a history of high health claims. Based on the information about *A* and *A*'s dependents, the issuer excludes *A* and *A*'s dependents from the group policy it offers to the employer.

(ii) *Conclusion.* See *Example 4* in 29 CFR 2590.702(b)(1) and 45 CFR 146.121(b)(1) for a conclusion that the exclusion by the issuer of *A* and *A*'s dependents from coverage is a rule for eligibility that discriminates based on one or more health factors and violates rules under 29 CFR 2590.702(b)(1) and 45 CFR 146.121(b)(1) similar to the rules under this paragraph (b)(1). (If the employer is a small employer under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for *A* and *A*'s dependents through other means, the plan will also violate this paragraph (b)(1).

(2) *Application to benefits*—(i) *General rule*—(A) [Reserved] For further guidance, see § 54.9802–1(b)(2)(i)(A).

(B) However, benefits provided under a plan must be uniformly available to all similarly situated individuals (as described in paragraph (d) of this section). Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan may impose annual, lifetime, or other limits on benefits and may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In the case of a cost-sharing requirement, see also paragraph (b)(2)(ii) of this section, which permits variances in the application of a cost-sharing mechanism made available under a bona fide wellness program. (Whether any plan provision or practice with respect to benefits complies with this paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under any other provision of the Code, the Americans with Disabilities Act, or any other law, whether State or federal.)

(C) For purposes of this paragraph (b)(2)(i), a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(D) The rules of this paragraph (b)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan applies a $500,000 lifetime limit on all benefits to each participant or beneficiary covered under the plan. The limit is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1,* the limit does not violate this paragraph (b)(2)(i) because $500,000 of benefits are available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to all participants and beneficiaries and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* A group health plan has a $2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant *B* files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a $10,000 lifetime limit on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) *Conclusion.* Under the facts of this *Example 2,* the plan violates this paragraph (b)(2)(i) because the plan modification is directed at *B* based on *B*'s claim.

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual *C* is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about *C*'s adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that *C* has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for *C* for that condition. The exclusionary rider is made effective the first day of the next plan year.

(ii) *Conclusion.* See *Example 3* in 29 CFR 2590.702(b)(2)(i) and 45 CFR 146.121(b)(2)(i) for a conclusion that the issuer violates rules under 29 CFR 2590.702(b)(2)(i) and 45 CFR 146.121(b)(2)(i) similar to the rules under this paragraph (b)(2)(i) because the rider excluding benefits for the condition that *C* has is directed at *C* even though it applies by its terms to all participants and beneficiaries under the plan.

Example 4. (i) *Facts.* A group health plan has a $2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4,* the limit does not violate this paragraph (b)(2)(i) because $2000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 5. (i) *Facts.* A group health plan applies a $2 million lifetime limit on all benefits. However, the $2 million lifetime limit is reduced to $10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) *Conclusion.* In this *Example 5,* the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals.

Example 6. (i) *Facts.* A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 6,* the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 7. (i) *Facts.* Under a group health plan, doctor visits are generally subject to a $250 annual deductible and 20 percent coinsurance requirement. However, prenatal doctor visits are not subject to any deductible or coinsurance requirement. These rules are applied uniformly to all similarly situated individuals and are not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 7,* imposing different deductible and coinsurance requirements for prenatal doctor visits and other visits does not violate this paragraph (b)(2)(i) because a plan may establish different deductibles or coinsurance requirements for different services if the deductible or coinsurance requirement is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Cost-sharing mechanisms and wellness programs.* [Reserved] For further guidance, see § 54.9802–1(b)(2)(ii).

(iii) *Specific rule relating to source-of-injury exclusions*—(A) If a group health plan generally provides benefits for a type of injury, the plan may not deny benefits otherwise provided for treatment of the injury if the injury results from an act of domestic violence or a medical condition (including both physical and mental health conditions).

(B) The rules of this paragraph (b)(2)(iii) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or injuries sustained in connection with attempted suicide. Individual *D* suffers from depression and attempts suicide. As a result, *D* sustains injuries and is hospitalized for treatment of the injuries. Pursuant to the exclusion, the plan denies *D* benefits for treatment of the injuries.

(ii) *Conclusion.* In this *Example 1,* the suicide attempt is the result of a medical condition (depression). Accordingly, the denial of benefits for the treatments of *D*'s injuries violates the requirements of this paragraph (b)(2)(iii) because the plan provision excludes benefits for treatment of an injury resulting from a medical condition.

Example 2. (i) *Facts.* A group health plan provides benefits for head injuries generally. The plan also has a general exclusion for any injury sustained while participating in any of a number of recreational activities, including bungee jumping. However, this exclusion does not apply to any injury that results from a medical condition (nor from domestic violence). Participant *E* sustains a head injury while bungee jumping. The injury did not result from a medical condition (nor from domestic violence). Accordingly, the plan denies benefits for *E*'s head injury.

(ii) *Conclusion.* In this *Example 2,* the plan provision that denies benefits based on the source of an injury does not restrict benefits based on an act of domestic violence or any medical condition. Therefore, the provision is permissible under this paragraph (b)(2)(iii) and does not violate this section. (However, if the plan did not allow *E* to enroll in the plan (or applied different rules for eligibility to *E*) because *E* frequently participates in bungee jumping, the plan would violate paragraph (b)(1) of this section.)

(3) *Relationship to section 9801(a), (b), and (d).* (i) A preexisting condition exclusion is permitted under this section if it—

(A) Complies with section 9801(a), (b), and (d);

(B) Applies uniformly to all similarly situated individuals (as described in paragraph (d) of this section); and

(C) Is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. For purposes of this paragraph (b)(3)(i)(C), a plan amendment relating to a preexisting condition exclusion applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(ii) The rules of this paragraph (b)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion on all individuals enrolled in the plan. The exclusion applies to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. In addition, the exclusion generally extends for 12 months after an individual's enrollment date, but this 12-month period is offset by the number of days of an individual's creditable coverage in accordance with section 9801(a). There is nothing to indicate that the exclusion is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1,* even though the plan's preexisting condition exclusion discriminates against individuals based on one or more health factors, the preexisting condition exclusion does not violate this section because it applies uniformly to all similarly situated individuals, is not directed at individual participants or beneficiaries, and complies with section 9801(a), (b), and (d) (that is, the requirements relating to the six-month look-back period, the 12-month (or 18-month) maximum exclusion period, and the creditable coverage offset).

Example 2. (i) *Facts.* A group health plan excludes coverage for conditions with respect to which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. Under the plan, the preexisting condition exclusion generally extends for 12 months, offset by creditable coverage. However, if an individual has no claims in the first six months following enrollment, the remainder of the exclusion period is waived.

(ii) *Conclusion.* In this *Example 2,* the plan's preexisting condition exclusions violate this section because they do not meet the requirements of this paragraph (b)(3); specifically, they do not apply uniformly to all similarly situated individuals. The plan provisions do not apply uniformly to all similarly situated individuals because individuals who have medical claims during the first six months following enrollment are not treated the same as similarly situated individuals with no claims during that period. (Under paragraph (d) of this section, the groups cannot be treated as two separate groups of similarly situated individuals because the distinction is based on a health factor.)

(c) *Prohibited discrimination in premiums or contributions*—(1) *In general*—(i) [Reserved] For further guidance, see § 54.9802–1(c)(1)(i).

(ii) Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium or contribution rate. (For rules relating to cost-sharing mechanisms, see paragraph (b)(2) of this section (addressing benefits).)

(2) *Rules relating to premium rates*—(i) *Group rating based on health factors not restricted under this section.* [Reserved] For further guidance, see § 54.9802–1(c)(1)(i).

(ii) *List billing based on a health factor prohibited.* However, a group health plan may not quote or charge an employer (or an individual) a different premium for an individual in a group of similarly situated individuals based on a health factor. (But see paragraph (g) of this section permitting favorable treatment of individuals with adverse health factors.)

(iii) *Examples.* The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual F had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

(ii) *Conclusion.* See *Example 1* in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer does not violate the provisions of 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) similar to the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for *F* than for a similarly situated individual based on *F*'s claims experience.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that the issuer quotes the employer a higher premium rate for *F*, because of *F*'s claims experience, than for a similarly situated individual.

(ii) *Conclusion.* See *Example 2* in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer violates provisions of 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) similar to the provisions of this paragraph (c)(2). Moreover, even if the plan purchased the policy based on the quote but did not require a higher participant contribution for *F* than for a similarly situated individual, see *Example 2* in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer would still violate 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) (but in such a case the plan would not violate this paragraph (c)(2)).

(3) *Exception for bona fide wellness programs.* [Reserved] For further guidance, see § 54.9802–1(c)(3).

(d) *Similarly situated individuals.* The requirements of this section apply only within a group of individuals who are treated as similarly situated individuals. A plan may treat participants as a group of similarly situated individuals separate from beneficiaries. In addition, participants may be treated as two or more distinct groups of similarly situated individuals and beneficiaries may be treated as two or more distinct groups of similarly situated individuals in accordance with the rules of this paragraph (d). Moreover, if individuals have a choice of two or more benefit packages, individuals choosing one benefit package may be treated as one or more groups of similarly situated individuals distinct from individuals choosing another benefit package.

(1) *Participants.* Subject to paragraph (d)(3) of this section, a plan may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of participants is based on a bona fide employment-based classification consistent with the employer's usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to paragraph (d)(3) of this section, examples of classifications that, based on all the relevant facts and circumstances, may be bona fide include full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations. However, a classification based on any health factor is not a bona fide employment-based classification, unless the requirements of paragraph (g) of this section are satisfied (permitting favorable treatment of individuals with adverse health factors).

(2) *Beneficiaries*—(i) Subject to paragraph (d)(3) of this section, a plan may treat beneficiaries as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of beneficiaries is based on any of the following factors:

(A) A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage;

(B) Relationship to the participant (*e.g.*, as a spouse or as a dependent child);

(C) Marital status;

(D) With respect to children of a participant, age or student status; or

(E) Any other factor if the factor is not a health factor.

(ii) Paragraph (d)(2)(i) of this section does not prevent more favorable treatment of beneficiaries with adverse health factors in accordance with paragraph (g) of this section.

(3) *Discrimination directed at individuals.* Notwithstanding paragraphs (d)(1) and (2) of this section, if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries, the classification is not permitted under this paragraph (d), unless it is permitted under paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors). Thus, if an employer modified an employment-based classification to single out, based on a health factor, individual participants and beneficiaries and deny them health coverage, the new classification would not be permitted under this section.

(4) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the employer's ususal business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1,* treating the full-time and part-time employees as two separate groups of similarly situated individuals is permitted under this paragraph (d) because the classification is bona fide and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* Under a group health plan, coverage is made available to employees, their spouses, and their dependent children. However, coverage is made available to a dependent child only if the dependent child is under age 19 (or under age 25 if the child is continuously enrolled full-time in an institution of higher learning (full-time students)). There is no evidence to suggest that these classifications are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2,* treating spouses and dependent children differently by imposing an age limitation on dependent children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and dependent children is permitted under paragraph (d)(2) of this section and is not prohibited under paragraph (d)(3) of this section because it is not directed at individual participants or beneficiaries. It is also permissible to treat dependent children who are under age 19 (or full-time students under age 25) as a group of similarly situated individuals separate from those who are age 25 or older (or age 19 or older if they are not full-time students) because the classification is permitted under paragraph (d)(2) of this section and is not directed at individual participants or beneficiaries.

Example 3. (i) *Facts.* A university sponsors a group health plan that provides one health benefit package to faculty and another health benefit package to other staff. Faculty and staff are treated differently with respect to other employee benefits such as retirement benefits and leaves of absence. There is no evidence to suggest that the distinction is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 3,* the classification is permitted under this paragraph (d) because there is a distinction based on a bona fide employment-based classification consistent with the employer's usual business practice and the distinction is not directed at individual participants and beneficiaries.

Example 4. (i) *Facts.* An employer sponsors a group health plan that is available to all current employees. Former employees may also be eligible, but only if they complete a specified number of years of service, are enrolled under the plan at the time of termination of employment, and are continuously enrolled from that date. There is no evidence to suggest that these distinctions are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4,* imposing additional eligibility requirements on former employees is permitted because a classification that distinguishes between current and former employees is a bona fide employment-based classification that is permitted under this paragraph (d), provided that it is not directed at individual participants or beneficiaries. In addition, it is permissible to distinguish between former employees who satisfy the service requirement and those who do not, provided that the distinction is not directed at individual participants or beneficiaries. (However, former employees who do not satisfy the eligibility criteria may, nonetheless, be eligible for continued coverage pursuant to a COBRA continuation provision or similar State law.)

Example 5. (i) *Facts.* An employer sponsors a group health plan that provides the same benefit package to all seven employees of the employer. Six of the seven employees have the same job title and responsibilities, but Employee *G* has a different job title and different responsibilities. After *G* files an expensive claim for benefits under the plan, coverage under the plan is modified so that employees with *G*'s job title receive a different benefit package that includes a lower lifetime dollar limit than in the benefit package made available to the other six employees.

(ii) *Conclusion.* Under the facts of this *Example 5,* changing the coverage classification for *G* based on the existing employment classification for *G* is not permitted under this paragraph (d) because the creation of the new coverage classification for *G* is directed at *G* based on one or more health factors.

(e) *Nonconfinement and actively-at-work provisions*—(1) *Nonconfinement provisions*—(i) *General rule.* Under the rules of paragraphs (b) and (c) of this section, a plan may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is confined to a hospital or other health care institution. In addition, under the rules of paragraphs (b) and (c) of this section, a plan may not establish a rule for eligibility or set any individual's premium or contribution rate based on an individual's ability to engage in normal life activities, except to the extent permitted under paragraphs (e)(2)(ii) and (3) of this section (permitting plans, under certain circumstances, to distinguish among employees based on the performance of services).

(ii) *Examples.* The rules of this paragraph (e)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, coverage for employees and their dependents generally becomes effective on the first day of employment. However, coverage for a dependent who is confined to a hospital or other health care institution does not become effective until the confinement ends.

(ii) *Conclusion.* In this *Example 1,* the plan violates this paragraph (e)(1) because the plan delays the effective date of coverage for dependents based on confinement to a hospital or other health care institution.

Example 2. (i) *Facts.* In previous years, a group health plan has provided coverage through a group health insurance policy offered by Issuer *M.* However, for the current year, the plan provides coverage through a group health insurance policy offered by Issuer *N.* Under Issuer *N*'s policy, items and services provided in connection with the confinement of a dependent to a hospital or other health care institution are not covered if the confinement is covered under an extension of benefits clause from a previous health insurance issuer.

(ii) *Conclusion.* See *Example 2* in 29 CFR 2590.702(e)(1) and 45 CFR 146.121(e)(1) for a conclusion that Issuer *N* violates provisions of 29 CFR 2590.702(e)(1) and 45 CFR 146.121(e)(1) similar to the provisions of this paragraph (e)(1) because Issuer *N* restricts benefits based on whether a dependent is confined to a hospital or other health care institution that is covered under an extension of benefits from a previous issuer.

(2) *Actively-at-work and continuous service provisions*—(i) *General rule*—(A) Under the rules of paragraphs (b) and (c) of this section and subject to the exception for the first day of work in paragraph (e)(2)(ii) of this section, a plan may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor (such as being absent from work on sick leave) is treated, for purposes of the plan, as being actively at work.

(B) The rules of this paragraph (e)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, an employee generally becomes eligible to enroll 30 days after the first day of employment. However, if the employee is not actively at work on the first day after the end of the 30-day period, then eligibility for enrollment is delayed until the first day the employee is actively at work.

(ii) *Conclusion.* In this *Example 1*, the plan violates this paragraph (e)(2) (and thus also violates paragraph (b) of this section). However, the plan would not violate paragraph (e)(2) or (b) of this section if, under the plan, an absence due to any health factor is considered being actively at work.

Example 2. (i) *Facts.* Under a group health plan, coverage for an employee becomes effective after 90 days of continuous service; that is, if an employee is absent from work (for any reason) before completing 90 days of service, the beginning of the 90-day period is measured from the day the employee returns to work (without any credit for service before the absence).

(ii) *Conclusion.* In this *Example 2,* the plan violates this paragraph (e)(2) (and thus also paragraph (b) of this section) because the 90-day continuous service requirement is a rule for eligibility based on whether an individual is actively at work. However, the plan would not violate this paragraph (e)(2) or paragraph (b) of this section if, under the plan, an absence due to any health factor is not considered an absence for purposes of measuring 90 days of continuous service.

(ii) *Exception for the first day of work*—(A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

(B) The rules of this paragraph (e)(2)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Under the eligibility provision of a group health plan, coverage for new employees becomes effective on the first day that the employee reports to work. Individual *H* is scheduled to begin work on August 3. However, *H* is unable to begin work on that day because of illness. *H* begins working on August 4, and *H*'s coverage is effective on August 4.

(ii) *Conclusion.* In this *Example 1,* the plan provision does not violate this section. However, if coverage for individuals who do not report to work on the first day they were scheduled to work for a reason unrelated to a health factor (such as vacation or bereavement) becomes effective on the first day they were scheduled to work, then the plan would violate this section.

Example 2. (i) *Facts.* Under a group health plan, coverage for new employees becomes effective on the first day of the month following the employee's first day of work, regardless of whether the employee is actively at work on the first day of the month. Individual *J* is scheduled to begin work on March 24. However, *J* is unable to begin work on March 24 because of illness. *J* begins working on April 7 and *J*'s coverage is effective May 1.

(ii) *Conclusion.* In this *Example 2,* the plan provision does not violate this section. However, as in *Example 1,* if coverage for individuals absent from work for reasons unrelated to a health factor became effective despite their absence, then the plan would violate this section.

(3) *Relationship to plan provisions defining similarly situated individuals*—(i) Notwithstanding the rules of paragraphs (e)(1) and (2) of this section, a plan may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in paragraph (d) of this section. Accordingly, a plan may distinguish in rules for eligibility under the plan between full-time and part-time employees, between permanent and temporary or seasonal employees, between current and former employees, and between employees currently performing services and employees no longer performing services for the employer, subject to paragraph (d) of this section. However, other federal or State laws (including the COBRA continuation provisions and the Family and Medical Leave Act of 1993) may require an employee or the employee's dependents to be offered coverage and set limits on the premium or contribution rate even though the employee is not performing services.

(ii) The rules of this paragraph (e)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, employees are eligible for coverage if they perform services for the employer for 30 or more hours per week or if they are on paid leave (such as annual, sick, or bereavement leave). Employees on unpaid leave are treated as a separate group of similarly situated individuals in accordance with the rules of paragraph (d) of this section.

(ii) *Conclusion.* In this *Example 1,* the plan provisions do not violate this section. However, if the plan treated individuals performing services for the employer for 30 or more hours per week, individuals on annual leave, and individuals on bereavement leave as a group of similarly situated individuals separate from individuals on sick leave, the plan would violate this paragraph (e) (and thus also would violate paragraph (b) of this section) because groups of similarly situated individuals cannot be established based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

Example 2. (i) *Facts.* To be eligible for coverage under a bona fide collectively bargained group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the three-month period that ends one month before the beginning of the current calendar quarter. The distinction between employees working at least 250 hours and those working less than 250 hours in the earlier three-month period is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2,* the plan provision does not violate this section because, under the rules for similarly situated individuals allowing full-time employees to be treated differently than part-time employees, employees who work at least 250 hours in a three-month period can be treated differently than employees who fail to work 250 hours in that period. The result would be the same if the plan permitted individuals to apply excess hours from previous periods to satisfy the requirement for the current quarter.

Example 3. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee *B* has been covered under the plan. *B* experiences a disabling illness that prevents *B* from working. *B* takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, *B* terminates employment and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 3,* the plan provision terminating *B*'s coverage upon *B*'s termination of employment does not violate this section.

Example 4. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the employee ceases to perform services for the employer sponsoring the plan, in accordance with the rules of paragraph (d) of this section. Employee *C* is laid off for three months. When the layoff begins, *C*'s coverage under the plan is terminated. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 4,* the plan provision terminating *C*'s coverage upon the cessation of *C*'s performance of services does not violate this section.

(f) *Bona fide wellness programs.* [Reserved]

(g) *More favorable treatment of individuals with adverse health factors permitted*—(1) *In rules for eligibility*—(i) Nothing in this section prevents a group health plan from establishing more favorable rules for eligibility (described in paragraph (b)(1) of this section) for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor. Moreover, nothing in this section prevents a plan from charging a higher premium or contribution with respect to individuals with an adverse health factor if they would not be eligible for the coverage were it not for the adverse health factor. (However, other laws, including State insurance laws, may set or limit premium rates; these laws are not affected by this section.)

(ii) The rules of this paragraph (g)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that generally is available to employees, spouses of employees, and dependent children until age 23. However, dependent children who are disabled are eligible for coverage beyond age 23.

(ii) *Conclusion.* In this *Example 1,* the plan provision allowing coverage for disabled dependent children beyond age 23 satisfies this paragraph (g)(1) (and thus does not violate this section).

Example 2. (i) *Facts.* An employer sponsors a group health plan, which is generally available to employees (and members of the employee's family) until the last day of the month in which the employee ceases to perform services for the employer. The plan generally charges employees $50 per month for employee-only coverage and $125 per month for family coverage. However, an employee who ceases to perform services for the employer by reason of disability may remain covered under the plan until the last day of the month that is 12 months after the month in which the employee ceased to perform services for the employer. During this extended period of coverage, the plan charges the employee $100 per month for employee-only coverage and $250 per month for family coverage. (This extended period of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 2,* the plan provision allowing extended coverage for disabled employees and their families satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled employees a higher premium during the extended period of coverage.

Example 3. (i) *Facts.* To comply with the requirements of a COBRA continuation provision, a group health plan generally makes COBRA continuation coverage available for a maximum period of 18 months in connection with a termination of employment but makes the coverage available for a maximum period of 29 months to certain disabled individuals and certain members of the disabled individual's family. Although the plan generally requires payment of 102 percent of the applicable premium for the first 18 months of COBRA continuation coverage, the plan requires payment of 150 percent of the applicable premium for the disabled individual's COBRA continuation coverage during the disability extension if the disabled individual would not be entitled to COBRA continuation coverage but for the disability.

(ii) *Conclusion.* In this *Example 3,* the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)

(2) *In premiums or contributions*—(i) Nothing in this section prevents a group health plan from charging individuals a premium or contribution that is less than the premium (or contribution) for similarly situated individuals if the lower charge is based on an adverse health factor, such as disability.

(ii) The rules of this paragraph (g)(2) are illustrated by the following example:

Example. (i) *Facts.* Under a group health plan, employees are generally required to pay $50 per month for employee-only coverage and $125 per month for family coverage under the plan. However, employees who are disabled receive coverage (whether employee-only or family coverage) under the plan free of charge.

(ii) *Conclusion.* In this *Example,* the plan provision waiving premium payment for disabled employees is permitted under this paragraph (g)(2) (and thus does not violate this section).

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of the Code (including the COBRA continuation provisions) or any other State or federal law, such as the Americans with Disabilities Act. Therefore, although the rules of this section would not prohibit a plan or issuer from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other

federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.

(i) *Effective dates*—(1) Final rules apply March 9, 2001. [Reserved] For further guidance, see § 54.9802–1(i)(1).

(2) *This section applies for plan years beginning on or after July 1, 2001.* Except as provided in paragraph (i)(3) of this section, this section applies for plan years beginning on or after July 1, 2001. Except as provided in paragraph (i)(3) of this section, with respect to efforts to comply with section 9802 before the first plan year beginning on or after July 1, 2001, the Secretary will not take any enforcement action against a plan that has sought to comply in good faith with section 9802.

(3) *Transitional rules for individuals previously denied coverage based on a health factor.* This paragraph (i)(3) provides rules relating to individuals previously denied coverage under a group health plan based on a health factor of the individual. Paragraph (i)(3)(i) clarifies what constitutes a denial of coverage under this paragraph (i)(3). Paragraph (i)(3)(ii) of this section applies with respect to any individual who was denied coverage if the denial was not based on a good faith interpretation of section 9802 or the Secretary's published guidance. Under that paragraph, such an individual must be allowed to enroll retroactively to the effective date of section 9802, or, if later, the date the individual meets eligibility criteria under the plan that do not discriminate based on any health factor. Paragraph (i)(3)(iii) of this section applies with respect to any individual who was denied coverage based on a good faith interpretation of section 9802 or the Secretary's published guidance. Under that paragraph, such an individual must be given an opportunity to enroll effective July 1, 2001. In either event, whether under paragraph (i)(3)(ii) or (iii) of this section, the Secretary will not take any enforcement action with respect to denials of coverage addressed in this paragraph (i)(3) if the plan has complied with the transitional rules of this paragraph (i)(3).

(i) *Denial of coverage clarified.* For purposes of this paragraph (i)(3), an individual is considered to have been denied coverage if the individual—

(A) Failed to apply for coverage because it was reasonable to believe that an application for coverage would have been futile due to a plan provision that discriminated based on a health factor; or

(B) Was not offered an opportunity to enroll in the plan and the failure to give such an opportunity violates this section.

(ii) *Individuals denied coverage without a good faith interpretation of the law*—(A) *Opportunity to enroll required.* If a plan has denied coverage to any individual based on a health factor and that denial was not based on a good faith interpretation of section 9802 or any guidance published by the Secretary, the plan is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days. This opportunity must be presented not later than March 9, 2001.

(*1*) If this enrollment opportunity was presented before or within the first plan year beginning on or after July 1, 1997 (or in the case of a collectively bargained plan, before or within the first plan year beginning on the effective date for the plan described in section 401(c)(3) of the Health Insurance Portability and Accountability Act of 1996), the coverage must be effective within that first plan year.

(*2*) If this enrollment opportunity is presented after such plan year, the individual must be given the choice of having the coverage effective on either of the following two dates—

(*i*) The date the plan receives a request for enrollment in connection with the enrollment opportunity; or

(*ii*) Retroactively to the first day of the first plan year beginning on the effective date for the plan described in section 401(c)(1) or (3) of the Health Insurance Portability and Accountability Act of 1996 (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). If an individual elects retroactive coverage, the plan is required to provide the benefits it would have provided if the individual had been enrolled for coverage during that period (irrespective of any otherwise applicable plan provisions governing timing for the submission of claims). The plan may require the individual to pay whatever additional amount the individual would have been required to pay for the coverage (but the plan cannot charge interest on that amount).

(B) *Relation to preexisting condition rules.* For purposes of Chapter 100 of Subtitle K, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date is the effective date for the plan described in section 401(c)(1) or (3) of the Health Insurance Portability and Accountability Act of 1996 (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan), even if the individual chooses under paragraph (i)(3)(ii)(A) of this section to have coverage effective only prospectively. In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

(C) *Examples.* The rules of this paragraph (i)(3)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *X* maintains a group health plan with a plan year beginning October 1 and ending September 30. Individual *F* was hired by Employer *X* before the effective date of section 9802. Before the effective date of section 9802 for this plan (October 1, 1997), the terms of the plan allowed employees and their dependents to enroll when the employee was first hired, and on each January 1 thereafter, but in either case, only if the individual could pass a physical examination. *F*'s application to enroll when first hired was denied because *F* could not pass a physical examination. Upon the effective date of section 9802 for this plan (October 1, 1997), the plan is amended to delete the requirement to pass a physical examination. In November of 1997, the plan gives *F* an opportunity to enroll in the plan (including notice of the opportunity to enroll) without passing a physical examination, with coverage effective January 1, 1998.

(ii) *Conclusion.* In this *Example 1,* the plan complies with the requirements of this paragraph (i)(3)(ii).

Example 2. (i) *Facts.* The plan year of a group health plan begins January 1 and ends December 31. Under the plan, a dependent who is unable to engage in normal life activities on the date coverage would otherwise become effective is not enrolled until the dependent is able to engage in normal life activities. Individual *G* is a dependent who is otherwise eligible for coverage, but is unable to engage in normal life activities. The plan has not allowed *G* to enroll for coverage.

(ii) *Conclusion.* In this *Example 2,* beginning on the effective date of section 9802 for the plan (January 1, 1998), the plan provision is not permitted under any good faith interpretation of section 9802 or any guidance published by the Secretary. Therefore, the plan is required, not later than March 9, 2001, to give *G* an opportunity to enroll (including notice of the opportunity to enroll), with coverage effective, at *G*'s option, either retroactively from January 1, 1998 or prospectively from the date *G*'s request for enrollment is received by the plan. If *G* elects coverage to be effective beginning January 1,

1998, the plan can require *G* to pay employee premiums for the retroactive coverage.

(iii) *Individuals denied coverage based on a good faith interpretation of the law*—(A) *Opportunity to enroll required.* If a plan has denied coverage to any individual before the first day of the first plan year beginning on or after July 1, 2001 based in part on a health factor and that denial was based on a good faith interpretation of section 9802 or guidance published by the Secretary, the plan is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, with coverage effective no later than July 1, 2001. Individuals required to be offered an opportunity to enroll include individuals previously offered enrollment without regard to a health factor but subsequently denied enrollment due to a health factor.

(B) *Relation to preexisting condition rules.* For purposes of Chapter 100 of Subtitle K, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date under the plan is the effective date for the plan described in section 401(c)(1) or (3) of the Health Insurance Portability and Accountability Act of 1996 (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

(C) *Example.* The rules of this paragraph (i)(3)(iii) are illustrated by the following example:

Example. (i) *Facts.* Individual *H* was hired by Employer *Y* on May 3, 1995. *Y* maintains a group health plan with a plan year beginning on February 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired (without a requirement to pass a physical examination), and on each February 1 thereafter if the individual can pass a physical examination. *H* chose not to enroll for coverage when hired in May of 1995. On February 1, 1997, *H* tried to enroll for coverage under the plan. However, *H* was denied coverage for failure to pass a physical examination. Shortly thereafter, *Y*'s plan eliminated late enrollment, and *H* was not given another opportunity to enroll in the plan. There is no evidence to suggest that *Y*'s plan was acting in bad faith in denying coverage under the plan beginning on the effective date of section 9802 (February 1, 1998).

(ii) *Conclusion.* In this *Example,* because coverage previously had been made available with respect to *H* without regard to any health factor of *H* and because *Y*'s plan was acting in accordance with a good faith interpretation of section 9802 (and guidance published by the Secretary), the failure of *Y*'s plan to allow *H* to enroll effective February 1, 1998 was permissible on that date. However, under the transitional rules of this paragraph (i)(3)(iii), *Y*'s plan must give *H* an opportunity to enroll that continues for at least 30 days, with coverage effective no later than July 1, 2001. (In addition, February 1, 1998 is *H*'s enrollment date under the plan and the period between February 1, 1998 and July 1, 2001 is treated as a waiting period. Accordingly, any preexisting condition exclusion period permitted under section 9801 will have expired before July 1, 2001.)

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved:

Dated: August 8, 2000.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

For the reasons set forth above, 29 CFR Part 2590 is amended as follows:

PART 2590 [AMENDED]—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 is revised to read as follows:

Authority: Secs. 107, 209, 505, 701–703, 711–713, and 731–734 of ERISA (29 U.S.C. 1027, 1059, 1135, 1171–1173, 1181–1183, and 1191–1194), as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436), section 101(g)(4) of HIPAA, and Secretary of Labor's Order No. 1–87, 52 FR 13139, April 21, 1987.

2. Section § 2590.702 is revised to read as follows:

§ 2590.702 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) *Health factors.* (1) The term *health factor* means, in relation to an individual, any of the following health status-related factors:

(i) Health status;

(ii) Medical condition (including both physical and mental illnesses), as defined in § 2590.701–2;

(iii) Claims experience;

(iv) Receipt of health care;

(v) Medical history;

(vi) Genetic information, as defined in § 2590.701–2;

(vii) Evidence of insurability; or

(viii) Disability.

(2) Evidence of insurability includes—

(i) Conditions arising out of acts of domestic violence; and

(ii) Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities.

(3) The decision whether health coverage is elected for an individual (including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor. (However, under § 2590.701–6, a plan or issuer must treat special enrollees the same as similarly situated individuals who are enrolled when first eligible.)

(b) *Prohibited discrimination in rules for eligibility*—(1) *In general*—(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not establish any rule for eligibility (including continued eligibility) of any individual to enroll for benefits under the terms of the plan or group health insurance coverage that discriminates based on any health factor that relates to that individual or a dependent of that individual. This rule is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (b)(3) of this section (allowing plans to impose certain preexisting condition exclusions), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to bona fide wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

(ii) For purposes of this section, rules for eligibility include, but are not limited to, rules relating to—

(A) Enrollment;

(B) The effective date of coverage;

(C) Waiting (or affiliation) periods;

(D) Late and special enrollment;

(E) Eligibility for benefit packages (including rules for individuals to change their selection among benefit packages);

(F) Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles), as described in paragraphs (b)(2) and (3) of this section;

(G) Continued eligibility; and

(H) Terminating coverage (including disenrollment) of any individual under the plan.

(iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, employees who do not enroll within the first

30 days cannot enroll later unless they pass a physical examination.

(ii) *Conclusion.* In this *Example 1*, the requirement to pass a physical examination in order to enroll in the plan is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 2. (i) *Facts.* Under an employer's group health plan, employees who enroll during the first 30 days of employment (and during special enrollment periods) may choose between two benefit packages: an indemnity option and an HMO option. However, employees who enroll during late enrollment are permitted to enroll only in the HMO option and only if they provide evidence of good health.

(ii) *Conclusion.* In this *Example 2*, the requirement to provide evidence of good health in order to be eligible for late enrollment in the HMO option is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1). However, if the plan did not require evidence of good health but limited late enrollees to the HMO option, the plan's rules for eligibility would not discriminate based on any health factor, and thus would not violate this paragraph (b)(1), because the time an individual chooses to enroll is not, itself, within the scope of any health factor.

Example 3. (i) *Facts.* Under an employer's group health plan, all employees generally may enroll within the first 30 days of employment. However, individuals who participate in certain recreational activities, including motorcycling, are excluded from coverage.

(ii) *Conclusion.* In this *Example 3*, excluding from the plan individuals who participate in recreational activities, such as motorcycling, is a rule for eligibility that discriminates based on one more health factors and thus violates this paragraph (b)(1).

Example 4. (i) *Facts.* A group health plan applies for a group health policy offered by an issuer. As part of the application, the issuer receives health information about individuals to be covered under the plan. Individual *A* is an employee of the employer maintaining the plan. *A* and *A*'s dependents have a history of high health claims. Based on the information about *A* and *A*'s dependents, the issuer excludes *A* and *A*'s dependents from the group policy it offers to the employer.

(ii) *Conclusion.* In this *Example 4*, the issuer's exclusion of *A* and *A*'s dependents from coverage is a rule for eligibility that discriminates based on one or more health factors, and thus violates this paragraph (b)(1). (If the employer is a small employer under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for *A* and *A*'s dependents through other means, the plan will also violate this paragraph (b)(1).

(2) *Application to benefits*—(i) *General rule*—(A) Under this section, a group health plan or group health insurance issuer is not required to provide coverage for any particular benefit to any group of similarly situated individuals.

(B) However, benefits provided under a plan or through group health insurance coverage must be uniformly available to all similarly situated individuals (as described in paragraph (d) of this section). Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan or issuer may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan or issuer may impose annual, lifetime, or other limits on benefits and may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In the case of a cost-sharing requirement, see also paragraph (b)(2)(ii) of this section, which permits variances in the application of a cost-sharing mechanism made available under a bona fide wellness program. (Whether any plan provision or practice with respect to benefits complies with this paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under any other provision of the Act, the Americans with Disabilities Act, or any other law, whether State or federal.)

(C) For purposes of this paragraph (b)(2)(i), a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(D) The rules of this paragraph (b)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan applies a $500,000 lifetime limit on all benefits to each participant or beneficiary covered under the plan. The limit is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1,* the limit does not violate this paragraph (b)(2)(i) because $500,000 of benefits are available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to all participants and beneficiaries and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* A group health plan has a $2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant *B* files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a $10,000 lifetime limit on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) *Conclusion.* Under the facts of this *Example 2,* the plan violates this paragraph (b)(2)(i) because the plan modification is directed at *B* based on *B*'s claim.

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual *C* is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about *C*'s adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that *C* has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for *C* for that condition. The exclusionary rider is made effective the first day of the next plan year.

(ii) *Conclusion.* In this *Example 3,* the issuer violates this paragraph (b)(2)(i) because benefits for *C*'s condition are available to other individuals in the group of similarly situated individuals that includes *C* but are not available to *C.* Thus, the benefits are not uniformly available to all similarly situated individuals. Even though the exclusionary rider is made effective the first day of the next plan year, because the rider does not apply to all similarly situated individuals, the issuer violates this paragraph (b)(2)(i).

Example 4. (i) *Facts.* A group health plan has a $2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4,* the limit does not violate this paragraph (b)(2)(i) because $2000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 5. (i) *Facts.* A group health plan applies a $2 million lifetime limit on all benefits. However, the $2 million lifetime limit is reduced to $10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) *Conclusion.* In this *Example 5,* the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals.

Example 6. (i) *Facts.* A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 6,* the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 7. (i) *Facts.* Under a group health plan, doctor visits are generally subject to a $250 annual deductible and 20 percent coinsurance requirement. However, prenatal doctor visits are not subject to any deductible or coinsurance requirement. These rules are applied uniformly to all similarly situated individuals and are not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 7,* imposing different deductible and coinsurance requirements for prenatal doctor visits and other visits does not violate this paragraph (b)(2)(i) because a plan may establish different deductibles or coinsurance requirements for different services if the deductible or coinsurance requirement is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Cost-sharing mechanisms and wellness programs.* A group health plan or group health insurance coverage with a cost-sharing mechanism (such as a deductible, copayment, or coinsurance) that requires a higher payment from an individual, based on a health factor of that individual or a dependent of that individual, than for a similarly situated individual under the plan (and thus does not apply uniformly to all similarly situated individuals) does not violate the requirements of this paragraph (b)(2) if the payment differential is based on whether an individual has complied with the requirements of a bona fide wellness program.

(iii) *Specific rule relating to source-of-injury exclusions*—(A) If a group health plan or group health insurance coverage generally provides benefits for a type of injury, the plan or issuer may not deny benefits otherwise provided for treatment of the injury if the injury results from an act of domestic violence or a medical condition (including both physical and mental health conditions).

(B) The rules of this paragraph (b)(2)(iii) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or injuries sustained in connection with attempted suicide. Individual *D* suffers from depression and attempts suicide. As a result, *D* sustains injuries and is hospitalized for treatment of the injuries. Pursuant to the exclusion, the plan denies *D* benefits for treatment of the injuries.

(ii) *Conclusion.* In this *Example 1,* the suicide attempt is the result of a medical condition (depression). Accordingly, the denial of benefits for the treatments of *D*'s injuries violates the requirements of this paragraph (b)(2)(iii) because the plan provision excludes benefits for treatment of an injury resulting from a medical condition.

Example 2. (i) *Facts.* A group health plan provides benefits for head injuries generally. The plan also has a general exclusion for any injury sustained while participating in any of a number of recreational activities, including bungee jumping. However, this exclusion does not apply to any injury that results from a medical condition (nor from domestic violence). Participant *E* sustains a head injury while bungee jumping. The injury did not result from a medical condition (nor from domestic violence). Accordingly, the plan denies benefits for *E*'s head injury.

(ii) *Conclusion.* In this *Example 2,* the plan provision that denies benefits based on the source of an injury does not restrict benefits based on an act of domestic violence or any medical condition. Therefore, the provision is permissible under this paragraph (b)(2)(iii) and does not violate this section. (However, if the plan did not allow *E* to enroll in the plan (or applied different rules for eligibility to *E*) because *E* frequently participates in bungee jumping, the plan would violate paragraph (b)(1) of this section.)

(3) *Relationship to § 2590.701–3.* (i) A preexisting condition exclusion is permitted under this section if it —

(A) Complies with § 2590.701–3;

(B) Applies uniformly to all similarly situated individuals (as described in paragraph (d) of this section); and

(C) Is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. For purposes of this paragraph (b)(3)(i)(C), a plan amendment relating to a preexisting condition exclusion applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(ii) The rules of this paragraph (b)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion on all individuals enrolled in the plan. The exclusion applies to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. In addition, the exclusion generally extends for 12 months after an individual's enrollment date, but this 12-month period is offset by the number of days of an individual's creditable coverage in accordance with § 2590.701–3. There is nothing to indicate that the exclusion is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1,* even though the plan's preexisting condition exclusion discriminates against individuals based on one or more health factors, the preexisting condition exclusion does not violate this section because it applies uniformly to all similarly situated individuals, is not directed at individual participants or beneficiaries, and complies with § 2590.701–3 (that is, the requirements relating to the six-month look-back period, the 12-month (or 18-month) maximum exclusion period, and the creditable coverage offset).

Example 2. (i) *Facts.* A group health plan excludes coverage for conditions with respect to which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. Under the plan, the preexisting condition exclusion generally extends for 12 months, offset by creditable coverage. However, if an individual has no claims in the first six months following enrollment, the remainder of the exclusion period is waived.

(ii) *Conclusion.* In this *Example 2,* the plan's preexisting condition exclusions violate this section because they do not meet the requirements of this paragraph (b)(3); specifically, they do not apply uniformly to all similarly situated individuals. The plan provisions do not apply uniformly to all similarly situated individuals because individuals who have medical claims during the first six months following enrollment are not treated the same as similarly situated individuals with no claims during that period. (Under paragraph (d) of this section, the groups cannot be treated as two separate groups of similarly situated individuals because the distinction is based on a health factor.)

(c) Prohibited discrimination in premiums or contributions—(1) *In general*—(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require an individual, as a condition of enrollment or continued enrollment under the plan or group health insurance coverage, to pay a premium or contribution that is

greater than the premium or contribution for a similarly situated individual (described in paragraph (d) of this section) enrolled in the plan or group health insurance coverage based on any health factor that relates to the individual or a dependent of the individual.

(ii) Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium or contribution rate. (For rules relating to cost-sharing mechanisms, see paragraph (b)(2) of this section (addressing benefits).)

(2) *Rules relating to premium rates*—(i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan.

(ii) *List billing based on a health factor prohibited.* However, a group health insurance issuer, or a group health plan, may not quote or charge an employer (or an individual) a different premium for an individual in a group of similarly situated individuals based on a health factor. (But see paragraph (g) of this section permitting favorable treatment of individuals with adverse health factors.)

(iii) *Examples.* The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual *F* had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

(ii) *Conclusion.* In this *Example 1,* the issuer does not violate the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for *F* than for a similarly situated individual based on *F*'s claims experience.

Example 2. (i) *Facts.* Same facts as *Example 1,* except that the issuer quotes the employer a higher premium rate for *F,* because of *F*'s claims experience, than for a similarly situated individual.

(ii) *Conclusion.* In this *Example 2,* the issuer violates this paragraph (c)(2). Moreover, even if the plan purchased the policy based on the quote but did not require a higher participant contribution for *F* than for a similarly situated individual, the issuer would still violate this paragraph (c)(2) (but in such a case the plan would not violate this paragraph (c)(2)).

(3) *Exception for bona fide wellness programs.* Notwithstanding paragraphs (c)(1) and (2) of this section, a plan may establish a premium or contribution differential based on whether an individual has complied with the requirements of a bona fide wellness program.

(d) *Similarly situated individuals.* The requirements of this section apply only within a group of individuals who are treated as similarly situated individuals. A plan or issuer may treat participants as a group of similarly situated individuals separate from beneficiaries. In addition, participants may be treated as two or more distinct groups of similarly situated individuals and beneficiaries may be treated as two or more distinct groups of similarly situated individuals in accordance with the rules of this paragraph (d). Moreover, if individuals have a choice of two or more benefit packages, individuals choosing one benefit package may be treated as one or more groups of similarly situated individuals distinct from individuals choosing another benefit package.

(1) *Participants.* Subject to paragraph (d)(3) of this section, a plan or issuer may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of participants is based on a bona fide employment-based classification consistent with the employer's usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to paragraph (d)(3) of this section, examples of classifications that, based on all the relevant facts and circumstances, may be bona fide include full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations. However, a classification based on any health factor is not a bona fide employment-based classification, unless the requirements of paragraph (g) of this section are satisfied (permitting favorable treatment of individuals with adverse health factors).

(2) *Beneficiaries*—(i) Subject to paragraph (d)(3) of this section, a plan or issuer may treat beneficiaries as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of beneficiaries is based on any of the following factors:

(A) A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage;

(B) Relationship to the participant (e.g., as a spouse or as a dependent child);

(C) Marital status;

(D) With respect to children of a participant, age or student status; or

(E) Any other factor if the factor is not a health factor.

(ii) Paragraph (d)(2)(i) of this section does not prevent more favorable treatment of individuals with adverse health factors in accordance with paragraph (g) of this section.

(3) *Discrimination directed at individuals.* Notwithstanding paragraphs (d)(1) and (2) of this section, if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries, the classification is not permitted under this paragraph (d), unless it is permitted under paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors). Thus, if an employer modified an employment-based classification to single out, based on a health factor, individual participants and beneficiaries and deny them health coverage, the new classification would not be permitted under this section.

(4) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the employer's ususal business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1,* treating the full-time and part-time employees as two separate groups of similarly situated individuals is permitted under this paragraph (d) because the classification is bona fide and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* Under a group health plan, coverage is made available to employees, their spouses, and their dependent children. However, coverage is made available to a dependent child only if the dependent child is under age 19 (or under age 25 if the child is continuously enrolled full-time in an institution of higher learning (full-time students)). There is no evidence to suggest that these classifications are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2,* treating spouses and dependent children differently by imposing an age limitation on dependent children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and dependent children is permitted under paragraph (d)(2) of this section and is not prohibited under paragraph (d)(3) of this section because it is not directed at individual participants or beneficiaries. It is also permissible to treat dependent children who are under age 19 (or full-time students under age 25) as a group of similarly situated individuals separate from those who are age 25 or older (or age 19 or older if they are not full-time students) because the classification is permitted under paragraph (d)(2) of this section and is not directed at individual participants or beneficiaries.

Example 3. (i) *Facts.* A university sponsors a group health plan that provides one health benefit package to faculty and another health benefit package to other staff. Faculty and staff are treated differently with respect to other employee benefits such as retirement benefits and leaves of absence. There is no evidence to suggest that the distinction is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 3,* the classification is permitted under this paragraph (d) because there is a distinction based on a bona fide employment-based classification consistent with the employer's usual business practice and the distinction is not directed at individual participants and beneficiaries.

Example 4. (i) *Facts.* An employer sponsors a group health plan that is available to all current employees. Former employees may also be eligible, but only if they complete a specified number of years of service, are enrolled under the plan at the time of termination of employment, and are continuously enrolled from that date. There is no evidence to suggest that these distinctions are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4,* imposing additional eligibility requirements on former employees is permitted because a classification that distinguishes between current and former employees is a bona fide employment-based classification that is permitted under this paragraph (d), provided that it is not directed at individual participants or beneficiaries. In addition, it is permissible to distinguish between former employees who satisfy the service requirement and those who do not, provided that the distinction is not directed at individual participants or beneficiaries. (However, former employees who do not satisfy the eligibility criteria may, nonetheless, be eligible for continued coverage pursuant to a COBRA continuation provision or similar State law.)

Example 5. (i) *Facts.* An employer sponsors a group health plan that provides the same benefit package to all seven employees of the employer. Six of the seven employees have the same job title and responsibilities, but Employee *G* has a different job title and different responsibilities. After *G* files an expensive claim for benefits under the plan, coverage under the plan is modified so that employees with *G*'s job title receive a different benefit package that includes a lower lifetime dollar limit than in the benefit package made available to the other six employees.

(ii) *Conclusion.* Under the facts of this *Example 5,* changing the coverage classification for *G* based on the existing employment classification for *G* is not permitted under this paragraph (d) because the creation of the new coverage classification for *G* is directed at *G* based on one or more health factors.

(e) *Nonconfinement and actively-at-work provisions*—(1) *Nonconfinement provisions*—(i) *General rule.* Under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is confined to a hospital or other health care institution. In addition, under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility or set any individual's premium or contribution rate based on an individual's ability to engage in normal life activities, except to the extent permitted under paragraphs (e)(2)(ii) and (3) of this section (permitting plans and issuers, under certain circumstances, to distinguish among employees based on the performance of services).

(ii) *Examples.* The rules of this paragraph (e)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, coverage for employees and their dependents generally becomes effective on the first day of employment. However, coverage for a dependent who is confined to a hospital or other health care institution does not become effective until the confinement ends.

(ii) *Conclusion.* In this *Example 1,* the plan violates this paragraph (e)(1) because the plan delays the effective date of coverage for dependents based on confinement to a hospital or other health care institution.

Example 2. (i) *Facts.* In previous years, a group health plan has provided coverage through a group health insurance policy offered by Issuer *M.* However, for the current year, the plan provides coverage through a group health insurance policy offered by Issuer *N.* Under Issuer *N*'s policy, items and services provided in connection with the confinement of a dependent to a hospital or other health care institution are not covered if the confinement is covered under an extension of benefits clause from a previous health insurance issuer.

(ii) *Conclusion.* In this *Example 2,* Issuer *N* violates this paragraph (e)(1) because the group health insurance coverage restricts benefits (a rule for eligibility under paragraph (b)(1)) based on whether a dependent is confined to a hospital or other health care institution that is covered under an extension of benefits clause from a previous issuer. This section does not affect any obligation Issuer M may have under applicable State law to provide any extension of benefits and does not affect any State law governing coordination of benefits.

(2) *Actively-at-work and continuous service provisions*—(i) *General rule*—(A) Under the rules of paragraphs (b) and (c) of this section and subject to the exception for the first day of work described in paragraph (e)(2)(ii) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor (such as being absent from work on sick leave) is treated, for purposes of the plan or health insurance coverage, as being actively at work.

(B) The rules of this paragraph (e)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, an employee generally becomes eligible to enroll 30 days after the first day of employment. However, if the employee is not actively at work on the first day after the end of the 30-day period, then eligibility for enrollment is delayed until the first day the employee is actively at work.

(ii) *Conclusion.* In this *Example 1,* the plan violates this paragraph (e)(2) (and thus also violates paragraph (b) of this section). However, the plan would not violate paragraph (e)(2) or (b) of this section if, under the plan, an absence due to any health factor is considered being actively at work.

Example 2. (i) *Facts.* Under a group health plan, coverage for an employee becomes effective after 90 days of continuous service; that is, if an employee is absent from work (for any reason) before completing 90 days of service, the beginning of the 90-day period is measured from the day the employee returns to work (without any credit for service before the absence).

(ii) *Conclusion.* In this *Example 2,* the plan violates this paragraph (e)(2) (and thus also paragraph (b) of this section) because the 90-day continuous service requirement is a rule for eligibility based on whether an individual is actively at work. However, the plan would not violate this paragraph (e)(2) or paragraph (b) of this section if, under the plan, an absence due to any health factor is not considered an absence for purposes of measuring 90 days of continuous service.

(ii) *Exception for the first day of work*—(A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan or issuer may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in

covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

(B) The rules of this paragraph (e)(2)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Under the eligibility provision of a group health plan, coverage for new employees becomes effective on the first day that the employee reports to work. Individual *H* is scheduled to begin work on August 3. However, *H* is unable to begin work on that day because of illness. *H* begins working on August 4, and *H*'s coverage is effective on August 4.

(ii) *Conclusion.* In this *Example 1,* the plan provision does not violate this section. However, if coverage for individuals who do not report to work on the first day they were scheduled to work for a reason unrelated to a health factor (such as vacation or bereavement) becomes effective on the first day they were scheduled to work, then the plan would violate this section.

Example 2. (i) *Facts.* Under a group health plan, coverage for new employees becomes effective on the first day of the month following the employee's first day of work, regardless of whether the employee is actively at work on the first day of the month. Individual *J* is scheduled to begin work on March 24. However, *J* is unable to begin work on March 24 because of illness. *J* begins working on April 7 and *J*'s coverage is effective May 1.

(ii) *Conclusion.* In this *Example 2,* the plan provision does not violate this section. However, as in *Example 1,* if coverage for individuals absent from work for reasons unrelated to a health factor became effective despite their absence, then the plan would violate this section.

(3) *Relationship to plan provisions defining similarly situated individuals*—(i) Notwithstanding the rules of paragraphs (e)(1) and (2) of this section, a plan or issuer may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in paragraph (d) of this section. Accordingly, a plan or issuer may distinguish in rules for eligibility under the plan between full-time and part-time employees, between permanent and temporary or seasonal employees, between current and former employees, and between employees currently performing services and employees no longer performing services for the employer, subject to paragraph (d) of this section. However, other federal or State laws (including the COBRA continuation provisions and the Family and Medical Leave Act of 1993) may require an employee or the employee's dependents to be offered coverage and set limits on the premium or contribution rate even though the employee is not performing services.

(ii) The rules of this paragraph (e)(3) are illustrated by the following examples:

Example 1. (i) Facts. Under a group health plan, employees are eligible for coverage if they perform services for the employer for 30 or more hours per week or if they are on paid leave (such as vacation, sick, or bereavement leave). Employees on unpaid leave are treated as a separate group of similarly situated individuals in accordance with the rules of paragraph (d) of this section.

(ii) *Conclusion.* In this *Example 1,* the plan provisions do not violate this section. However, if the plan treated individuals performing services for the employer for 30 or more hours per week, individuals on vacation leave, and individuals on bereavement leave as a group of similarly situated individuals separate from individuals on sick leave, the plan would violate this paragraph (e) (and thus also would violate paragraph (b) of this section) because groups of similarly situated individuals cannot be established based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

Example 2. (i) *Facts.* To be eligible for coverage under a bona fide collectively bargained group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the three-month period that ends one month before the beginning of the current calendar quarter. The distinction between employees working at least 250 hours and those working less than 250 hours in the earlier three-month period is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2,* the plan provision does not violate this section because, under the rules for similarly situated individuals allowing full-time employees to be treated differently than part-time employees, employees who work at least 250 hours in a three-month period can be treated differently than employees who fail to work 250 hours in that period. The result would be the same if the plan permitted individuals to apply excess hours from previous periods to satisfy the requirement for the current quarter.

Example 3. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee *B* has been covered under the plan. *B* experiences a disabling illness that prevents *B* from working. *B* takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, *B* terminates employment and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 3,* the plan provision terminating *B*'s coverage upon *B*'s termination of employment does not violate this section.

Example 4. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the employee ceases to perform services for the employer sponsoring the plan, in accordance with the rules of paragraph (d) of this section. Employee *C* is laid off for three months. When the layoff begins, *C*'s coverage under the plan is terminated. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 4,* the plan provision terminating *C*'s coverage upon the cessation of *C*'s performance of services does not violate this section.

(f) *Bona fide wellness programs.* [Reserved.]

(g) *More favorable treatment of individuals with adverse health factors permitted*—(1) *In rules for eligibility*—(i) Nothing in this section prevents a group health plan or group health insurance issuer from establishing more favorable rules for eligibility (described in paragraph (b)(1) of this section) for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor. Moreover, nothing in this section prevents a plan or issuer from charging a higher premium or contribution with respect to individuals with an adverse health factor if they would not be eligible for the coverage were it not for the adverse health factor. (However, other laws, including State insurance laws, may set or limit premium rates; these laws are not affected by this section.)

(ii) The rules of this paragraph (g)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that generally is available to employees, spouses of employees, and dependent children until age 23. However, dependent children who are disabled are eligible for coverage beyond age 23.

(ii) *Conclusion.* In this *Example 1,* the plan provision allowing coverage for disabled dependent children beyond age 23 satisfies this paragraph (g)(1) (and thus does not violate this section).

Example 2. (i) *Facts.* An employer sponsors a group health plan, which is generally available to employees (and members of the employee's family) until the last day of the month in which the employee ceases to perform services for the employer. The plan generally charges employees $50 per month for employee-only coverage and $125 per month for family coverage. However, an employee who ceases to perform services for the employer by reason of disability may remain covered under the plan until the last day of the month that is 12 months after the month in which the employee ceased to perform services for the employer. During this extended period of coverage, the plan charges the employee $100 per month for employee-only coverage and $250 per month

for family coverage. (This extended period of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 2,* the plan provision allowing extended coverage for disabled employees and their families satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled employees a higher premium during the extended period of coverage.

Example 3. (i) *Facts.* To comply with the requirements of a COBRA continuation provision, a group health plan generally makes COBRA continuation coverage available for a maximum period of 18 months in connection with a termination of employment but makes the coverage available for a maximum period of 29 months to certain disabled individuals and certain members of the disabled individual's family. Although the plan generally requires payment of 102 percent of the applicable premium for the first 18 months of COBRA continuation coverage, the plan requires payment of 150 percent of the applicable premium for the disabled individual's COBRA continuation coverage during the disability extension if the disabled individual would not be entitled to COBRA continuation coverage but for the disability.

(ii) *Conclusion.* In this *Example 3,* the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)

(2) *In premiums or contributions*—(i) Nothing in this section prevents a group health plan or group health insurance issuer from charging individuals a premium or contribution that is less than the premium (or contribution) for similarly situated individuals if the lower charge is based on an adverse health factor, such as disability.

(ii) The rules of this paragraph (g)(2) are illustrated by the following example:

Example. (i) *Facts.* Under a group health plan, employees are generally required to pay $50 per month for employee-only coverage and $125 per month for family coverage under the plan. However, employees who are disabled receive coverage (whether employee-only or family coverage) under the plan free of charge.

(ii) *Conclusion.* In this *Example,* the plan provision waiving premium payment for disabled employees is permitted under this paragraph (g)(2) (and thus does not violate this section).

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of the Act (including the COBRA continuation provisions) or any other State or federal law, such as the Americans with Disabilities Act. Therefore, although the rules of this section would not prohibit a plan or issuer from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans and issuers, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.

(i) *Applicability dates*—(1) *Paragraphs applicable March 9, 2001.* Paragraphs (a)(1), (a)(2)(i), (b)(1)(i), (b)(1)(iii) *Example 1,* (b)(2)(i)(A), (b)(2)(ii), (c)(1)(i), (c)(2)(i), and (c)(3) of this section and this paragraph (*i*)(1) apply to group health plans and health insurance issuers offering group health insurance coverage March 9, 2001.

(2) *Paragraphs applicable for plan years beginning on or after July 1, 2001.* Except as provided in paragraph (*i*)(3) of this section, the provisions of this section not listed in paragraph (*i*)(1) of this section apply to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after July 1, 2001. Except as provided in paragraph (*i*)(3) of this section, with respect to efforts to comply with section 702 of the Act before the first plan year beginning on or after July 1, 2001, the Secretary will not take any enforcement action against a plan that has sought to comply in good faith with section 702 of the Act.

(3) *Transitional rules for individuals previously denied coverage based on a health factor.* This paragraph (*i*)(3) provides rules relating to individuals previously denied coverage under a group health plan or group health insurance coverage based on a health factor of the individual. Paragraph (*i*)(3)(i) clarifies what constitutes a denial of coverage under this paragraph (*i*)(3). Paragraph (*i*)(3)(ii) of this section applies with respect to any individual who was denied coverage if the denial was not based on a good faith interpretation of section 702 of the Act or the Secretary's published guidance. Under that paragraph, such an individual must be allowed to enroll retroactively to the effective date of section 702 of the Act, or, if later, the date the individual meets eligibility criteria under the plan that do not discriminate based on any health factor. Paragraph (*i*)(3)(iii) of this section applies with respect to any individual who was denied coverage based on a good faith interpretation of section 702 of the Act or the Secretary's published guidance. Under that paragraph, such an individual must be given an opportunity to enroll effective July 1, 2001. In either event, whether under paragraph (i)(3)(ii) or (iii) of this section, the Secretary will not take any enforcement action with respect to denials of coverage addressed in this paragraph (i)(3) if the plan has complied with the transitional rules of this paragraph (i)(3).

(i) *Denial of coverage clarified.* For purposes of this paragraph (i)(3), an individual is considered to have been denied coverage if the individual—

(A) Failed to apply for coverage because it was reasonable to believe that an application for coverage would have been futile due to a plan provision that discriminated based on a health factor; or

(B) Was not offered an opportunity to enroll in the plan and the failure to give such an opportunity violates this section.

(ii) *Individuals denied coverage without a good faith interpretation of the law*—(A) *Opportunity to enroll required.* If a plan or issuer has denied coverage to any individual based on a health factor and that denial was not based on a good faith interpretation of section 702 of the Act or any guidance published by the Secretary, the plan or issuer is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days. This opportunity must be presented not later than March 9, 2001.

(*1*) If this enrollment opportunity was presented before or within the first plan year beginning on or after July 1, 1997 (or in the case of a collectively bargained plan, before or within the first plan year beginning on the effective date for the plan described in section 101(g)(3) of the Health Insurance Portability and Accountability Act of 1996), the coverage must be effective within that first plan year.

(*2*) If this enrollment opportunity is presented after such plan year, the individual must be given the choice of

having the coverage effective on either of the following two dates—

(*i*) The date the plan receives a request for enrollment in connection with the enrollment opportunity; or

(*ii*) Retroactively to the first day of the first plan year beginning on the effective date for the plan described in sections 101(g)(1) and (3) of the Health Insurance Portability and Accountability Act of 1996 (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). If an individual elects retroactive coverage, the plan or issuer is required to provide the benefits it would have provided if the individual had been enrolled for coverage during that period (irrespective of any otherwise applicable plan provisions governing timing for the submission of claims). The plan or issuer may require the individual to pay whatever additional amount the individual would have been required to pay for the coverage (but the plan or issuer cannot charge interest on that amount).

(B) *Relation to preexisting condition rules.* For purposes of part 7 of subtitle B of title I of the Act, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date is the effective date for the plan described in sections 101(g)(1) and (3) of the Health Insurance Portability and Accountability Act (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan), even if the individual chooses under paragraph (i)(3)(ii)(A) of this section to have coverage effective only prospectively. In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

(C) *Examples.* The rules of this paragraph (i)(3)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *X* maintains a group health plan with a plan year beginning October 1 and ending September 30. Individual *F* was hired by Employer *X* before the effective date of section 702 of the Act. Before the effective date of section 702 of the Act for this plan (October 1, 1997), the terms of the plan allowed employees and their dependents to enroll when the employee was first hired, and on each January 1 thereafter, but in either case, only if the individual could pass a physical examination. *F*'s application to enroll when first hired was denied because *F* had diabetes and could not pass a physical examination. Upon the effective date of section 702 of the Act for this plan (October 1, 1997), the plan is amended to delete the requirement to pass a physical examination. In November of 1997, the plan gives *F* an opportunity to enroll in the plan (including notice of the opportunity to enroll) without passing a physical examination, with coverage effective January 1, 1998.

(ii) *Conclusion.* In this *Example 1,* the plan complies with the requirements of this paragraph (*i*)(3)(ii).

Example 2. (i) *Facts.* The plan year of a group health plan begins January 1 and ends December 31. Under the plan, a dependent who is unable to engage in normal life activities on the date coverage would otherwise become effective is not enrolled until the dependent is able to engage in normal life activities. Individual *G* is a dependent who is otherwise eligible for coverage, but is unable to engage in normal life activities. The plan has not allowed *G* to enroll for coverage.

(ii) *Conclusion.* In this *Example 2,* beginning on the effective date of section 702 of the Act for the plan (January 1, 1998), the plan provision is not permitted under any good faith interpretation of section 702 of the Act or any guidance published by the Secretary. Therefore, the plan is required, not later than March 9, 2001, to give *G* an opportunity to enroll (including notice of the opportunity to enroll), with coverage effective, at *G*'s option, either retroactively from January 1, 1998 or prospectively from the date *G*'s request for enrollment is received by the plan. If *G* elects coverage to be effective beginning January 1, 1998, the plan can require G to pay any required employee premiums for the retroactive coverage.

(iii) *Individuals denied coverage based on a good faith interpretation of the law*—(A) *Opportunity to enroll required.* If a plan or issuer has denied coverage to any individual before the first day of the first plan year beginning on or after July 1, 2001 based in part on a health factor and that denial was based on a good faith interpretation of section 702 of the Act or guidance published by the Secretary, the plan or issuer is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, with coverage effective no later than July 1, 2001. Individuals required to be offered an opportunity to enroll include individuals previously offered enrollment without regard to a health factor but subsequently denied enrollment due to a health factor.

(B) *Relation to preexisting condition rules.* For purposes of Part 7 of Subtitle B of Title I of the Act, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date is the effective date for the plan described in sections 101(g)(1) and (3) of the Health Insurance Portability and Accountability Act (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

(C) *Example.* The rules of this paragraph (*i*)(3)(iii) are illustrated by the following example:

Example. (i) *Facts.* Individual *H* was hired by Employer *Y* on May 3, 1995. *Y* maintains a group health plan with a plan year beginning on February 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired (without a requirement to pass a physical examination), and on each February 1 thereafter if the individual can pass a physical examination. *H* chose not to enroll for coverage when hired in May of 1995. On February 1, 1997, *H* tried to enroll for coverage under the plan. However, *H* was denied coverage for failure to pass a physical examination. Shortly thereafter, *Y*'s plan eliminated late enrollment, and *H* was not given another opportunity to enroll in the plan. There is no evidence to suggest that *Y*'s plan was acting in bad faith in denying coverage under the plan beginning on the effective date of section 702 of the Act (February 1, 1998).

(ii) *Conclusion.* In this *Example,* because coverage previously had been made available with respect to *H* without regard to any health factor of *H* and because *Y*'s plan was acting in accordance with a good faith interpretation of section 702 (and guidance published by the Secretary), the failure of *Y*'s plan to allow *H* to enroll effective February 1, 1998 was permissible on that date. However, under the transitional rules of this paragraph (*i*)(3)(iii), *Y*'s plan must give *H* an opportunity to enroll that continues for at least 30 days, with coverage effective no later than July 1, 2001. (In addition, February 1, 1998 is *H*'s enrollment date under the plan and the period between February 1, 1998 and July 1, 2001 is treated as a waiting period. Accordingly, any preexisting condition exclusion period permitted under § 2590.701–3 will have expired before July 1, 2001.)

3. The heading, paragraph (a)(1), and the first sentence of paragraph (a)(2) of § 2590.736 are revised to read as follows:

§ 2590.736 Applicability dates.

(a) *General applicability dates*—(1) *Non-collectively bargained plans.* Part 7 of Subtitle B of Title I of the Act and §§ 2590.701–1 through 2590.701–7, 2590.703, 2590.731 through 2590.734, and this section apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997, except as otherwise provided in this section.

(2) *Collectively-bargained plans.* Except as otherwise provided in this section (other than in paragraph (a)(1) of

this section), in the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before August 21, 1996, Part 7 of Subtitle B of Title I of the Act and §§ 2590.701–1 through 2590.701–7, 2590.703, 2590.731 through 2590.734, and this section do not apply to plan years beginning before the later of July 1, 1997, or the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after August 21, 1996). * * *

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Signed at Washington, DC this 28th day of December, 2000.

Leslie B. Kramerich,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

For the reasons set forth above, 45 CFR Part 146 is amended as follows:

PART 146 [AMENDED]—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 146 is revised to read as follows:

Authority: Secs. 2701 through 2763, 2791 and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92 as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436), and section 102(c)(4) of HIPAA.

2. Section 146.121 is revised to read as follows:

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) *Health factors.* (1) The term *health factor* means, in relation to an individual, any of the following health status-related factors:

(i) Health status;

(ii) Medical condition (including both physical and mental illnesses), as defined in § 144.103;

(iii) Claims experience;

(iv) Receipt of health care;

(v) Medical history;

(vi) Genetic information, as defined in 45 CFR 144.103;

(vii) Evidence of insurability; or

(viii) Disability.

(2) Evidence of insurability includes—

(i) Conditions arising out of acts of domestic violence; and

(ii) Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities.

(3) The decision whether health coverage is elected for an individual (including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor. (However, under § 146.117, a plan or issuer must treat special enrollees the same as similarly situated individuals who are enrolled when first eligible.)

(b) *Prohibited discrimination in rules for eligibility*—(1) *In general*—(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not establish any rule for eligibility (including continued eligibility) of any individual to enroll for benefits under the terms of the plan or group health insurance coverage that discriminates based on any health factor that relates to that individual or a dependent of that individual. This rule is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (b)(3) of this section (allowing plans to impose certain preexisting condition exclusions), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to bona fide wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

(ii) For purposes of this section, rules for eligibility include, but are not limited to, rules relating to—

(A) Enrollment;

(B) The effective date of coverage;

(C) Waiting (or affiliation) periods;

(D) Late and special enrollment;

(E) Eligibility for benefit packages (including rules for individuals to change their selection among benefit packages);

(F) Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles), as described in paragraphs (b) (2) and (3) of this section;

(G) Continued eligibility; and

(H) Terminating coverage (including disenrollment) of any individual under the plan.

(iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, employees who do not enroll within the first 30 days cannot enroll later unless they pass a physical examination.

(ii) *Conclusion.* In this *Example 1,* the requirement to pass a physical examination in order to enroll in the plan is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 2. (i) *Facts.* Under an employer's group health plan, employees who enroll during the first 30 days of employment (and during special enrollment periods) may choose between two benefit packages: an indemnity option and an HMO option. However, employees who enroll during late enrollment are permitted to enroll only in the HMO option and only if they provide evidence of good health.

(ii) *Conclusion.* In this *Example 2,* the requirement to provide evidence of good health in order to be eligible for late enrollment in the HMO option is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1). However, if the plan did not require evidence of good health but limited late enrollees to the HMO option, the plan's rules for eligibility would not discriminate based on any health factor, and thus would not violate this paragraph (b)(1), because the time an individual chooses to enroll is not, itself, within the scope of any health factor.

Example 3. (i) *Facts.* Under an employer's group health plan, all employees generally may enroll within the first 30 days of employment. However, individuals who participate in certain recreational activities, including motorcycling, are excluded from coverage.

(ii) *Conclusion.* In this *Example 3,* excluding from the plan individuals who participate in recreational activities, such as motorcycling, is a rule for eligibility that discriminates based on one more health factors and thus violates this paragraph (b)(1).

Example 4. (i) *Facts.* A group health plan applies for a group health policy offered by an issuer. As part of the application, the issuer receives health information about individuals to be covered under the plan. Individual *A* is an employee of the employer maintaining the plan. *A* and *A*'s dependents have a history of high health claims. Based on the information about *A* and *A*'s dependents, the issuer excludes *A* and *A*'s dependents from the group policy it offers to the employer.

(ii) *Conclusion.* In this *Example 4,* the issuer's exclusion of *A* and *A*'s dependents from coverage is a rule for eligibility that discriminates based on one or more health factors, and thus violates this paragraph (b)(1). (If the employer is a small employer under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible

individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for *A* and *A*'s dependents through other means, the plan will also violate this paragraph (b)(1).

(2) *Application to benefits*—(i) *General rule*—(A) Under this section, a group health plan or group health insurance issuer is not required to provide coverage for any particular benefit to any group of similarly situated individuals.

(B) However, benefits provided under a plan or through group health insurance coverage must be uniformly available to all similarly situated individuals (as described in paragraph (d) of this section). Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan or issuer may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan or issuer may impose annual, lifetime, or other limits on benefits and may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In the case of a cost-sharing requirement, see also paragraph (b)(2)(ii) of this section, which permits variances in the application of a cost-sharing mechanism made available under a bona fide wellness program. (Whether any plan provision or practice with respect to benefits complies with this paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under any other provision of ERISA, the Americans with Disabilities Act, or any other law, whether State or federal.)

(C) For purposes of this paragraph (b)(2)(i), a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(D) The rules of this paragraph (b)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan applies a $500,000 lifetime limit on all benefits to each participant or beneficiary covered under the plan. The limit is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, the limit does not violate this paragraph (b)(2)(i) because $500,000 of benefits are available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to all participants and beneficiaries and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* A group health plan has a $2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant *B* files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a $10,000 lifetime limit on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) *Conclusion.* Under the facts of this *Example 2*, the plan violates this paragraph (b)(2)(i) because the plan modification is directed at *B* based on *B*'s claim.

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual *C* is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about *C*'s adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that *C* has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for *C* for that condition. The exclusionary rider is made effective the first day of the next plan year.

(ii) *Conclusion.* In this *Example 3*, the issuer violates this paragraph (b)(2)(i) because benefits for *C*'s condition are available to other individuals in the group of similarly situated individuals that includes *C* but are not available to *C*. Thus, the benefits are not uniformly available to all similarly situated individuals. Even though the exclusionary rider is made effective the first day of the next plan year, because the rider does not apply to all similarly situated individuals, the issuer violates this paragraph (b)(2)(i).

Example 4. (i) *Facts.* A group health plan has a $2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4*, the limit does not violate this paragraph (b)(2)(i) because $2,000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 5. (i) *Facts.* A group health plan applies a $2 million lifetime limit on all benefits. However, the $2 million lifetime limit is reduced to $10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) *Conclusion.* In this *Example 5*, the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals.

Example 6. (i) *Facts.* A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 6*, the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 7. (i) *Facts.* Under a group health plan, doctor visits are generally subject to a $250 annual deductible and 20 percent coinsurance requirement. However, prenatal doctor visits are not subject to any deductible or coinsurance requirement. These rules are applied uniformly to all similarly situated individuals and are not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 7*, imposing different deductible and coinsurance requirements for prenatal doctor visits and other visits does not violate this paragraph (b)(2)(i) because a plan may establish different deductibles or coinsurance requirements for different services if the deductible or coinsurance requirement is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Cost-sharing mechanisms and wellness programs.* A group health plan or group health insurance coverage with a cost-sharing mechanism (such as a deductible, copayment, or coinsurance) that requires a higher payment from an individual, based on a health factor of that individual or a dependent of that individual, than for a similarly situated individual under the plan (and thus does not apply uniformly to all similarly situated individuals) does not violate the requirements of this paragraph (b)(2) if the payment differential is based on whether an individual has complied

with the requirements of a bona fide wellness program.

(iii) *Specific rule relating to source-of-injury exclusions*—(A) If a group health plan or group health insurance coverage generally provides benefits for a type of injury, the plan or issuer may not deny benefits otherwise provided for treatment of the injury if the injury results from an act of domestic violence or a medical condition (including both physical and mental health conditions).

(B) The rules of this paragraph (b)(2)(iii) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or injuries sustained in connection with attempted suicide. Individual *D* suffers from depression and attempts suicide. As a result, *D* sustains injuries and is hospitalized for treatment of the injuries. Pursuant to the exclusion, the plan denies *D* benefits for treatment of the injuries.

(ii) *Conclusion.* In this *Example 1*, the suicide attempt is the result of a medical condition (depression). Accordingly, the denial of benefits for the treatments of *D*'s injuries violates the requirements of this paragraph (b)(2)(iii) because the plan provision excludes benefits for treatment of an injury resulting from a medical condition.

Example 2. (i) *Facts.* A group health plan provides benefits for head injuries generally. The plan also has a general exclusion for any injury sustained while participating in any of a number of recreational activities, including bungee jumping. However, this exclusion does not apply to any injury that results from a medical condition (nor from domestic violence). Participant *E* sustains a head injury while bungee jumping. The injury did not result from a medical condition (nor from domestic violence). Accordingly, the plan denies benefits for *E*'s head injury.

(ii) *Conclusion.* In this *Example 2*, the plan provision that denies benefits based on the source of an injury does not restrict benefits based on an act of domestic violence or any medical condition. Therefore, the provision is permissible under this paragraph (b)(2)(iii) and does not violate this section. (However, if the plan did not allow *E* to enroll in the plan (or applied different rules for eligibility to *E*) because *E* frequently participates in bungee jumping, the plan would violate paragraph (b)(1) of this section.)

(3) *Relationship to § 146.111.* (i) A preexisting condition exclusion is permitted under this section if it—

(A) Complies with § 146.111;

(B) Applies uniformly to all similarly situated individuals (as described in paragraph (d) of this section); and

(C) Is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. For purposes of this paragraph (b)(3)(i)(C), a plan amendment relating to a preexisting condition exclusion applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(ii) The rules of this paragraph (b)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion on all individuals enrolled in the plan. The exclusion applies to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. In addition, the exclusion generally extends for 12 months after an individual's enrollment date, but this 12-month period is offset by the number of days of an individual's creditable coverage in accordance with § 146.111. There is nothing to indicate that the exclusion is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, even though the plan's preexisting condition exclusion discriminates against individuals based on one or more health factors, the preexisting condition exclusion does not violate this section because it applies uniformly to all similarly situated individuals, is not directed at individual participants or beneficiaries, and complies with § 146.111 (that is, the requirements relating to the six-month look-back period, the 12-month (or 18-month) maximum exclusion period, and the creditable coverage offset).

Example 2. (i) *Facts.* A group health plan excludes coverage for conditions with respect to which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. Under the plan, the preexisting condition exclusion generally extends for 12 months, offset by creditable coverage. However, if an individual has no claims in the first six months following enrollment, the remainder of the exclusion period is waived.

(ii) *Conclusion.* In this *Example 2*, the plan's preexisting condition exclusions violate this section because they do not meet the requirements of this paragraph (b)(3); specifically, they do not apply uniformly to all similarly situated individuals. The plan provisions do not apply uniformly to all similarly situated individuals because individuals who have medical claims during the first six months following enrollment are not treated the same as similarly situated individuals with no claims during that period. (Under paragraph (d) of this section, the groups cannot be treated as two separate groups of similarly situated individuals because the distinction is based on a health factor.)

(c) *Prohibited discrimination in premiums or contributions*—(1) *In general*—(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require an individual, as a condition of enrollment or continued enrollment under the plan or group health insurance coverage, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual (described in paragraph (d) of this section) enrolled in the plan or group health insurance coverage based on any health factor that relates to the individual or a dependent of the individual.

(ii) Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium or contribution rate. (For rules relating to cost-sharing mechanisms, see paragraph (b)(2) of this section (addressing benefits).)

(2) *Rules relating to premium rates*—(i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan.

(ii) *List billing based on a health factor prohibited.* However, a group health insurance issuer, or a group health plan, may not quote or charge an employer (or an individual) a different premium for an individual in a group of similarly situated individuals based on a health factor. (But see paragraph (g) of this section permitting favorable treatment of individuals with adverse health factors.)

(iii) *Examples.* The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual F had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

(ii) *Conclusion.* In this *Example 1*, the issuer does not violate the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for F than for a similarly situated individual based on *F*'s claims experience.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that the issuer quotes the employer a higher premium rate for *F*, because of *F*'s claims experience, than for a similarly situated individual.

(ii) *Conclusion.* In this *Example 2*, the issuer violates this paragraph (c)(2). Moreover, even if the plan purchased the policy based on the quote but did not require a higher participant contribution for *F* than

for a similarly situated individual, the issuer would still violate this paragraph (c)(2) (but in such a case the plan would not violate this paragraph (c)(2)).

(3) *Exception for bona fide wellness programs.* Notwithstanding paragraphs (c)(1) and (2) of this section, a plan may establish a premium or contribution differential based on whether an individual has complied with the requirements of a bona fide wellness program.

(d) *Similarly situated individuals.* The requirements of this section apply only within a group of individuals who are treated as similarly situated individuals. A plan or issuer may treat participants as a group of similarly situated individuals separate from beneficiaries. In addition, participants may be treated as two or more distinct groups of similarly situated individuals and beneficiaries may be treated as two or more distinct groups of similarly situated individuals in accordance with the rules of this paragraph (d). Moreover, if individuals have a choice of two or more benefit packages, individuals choosing one benefit package may be treated as one or more groups of similarly situated individuals distinct from individuals choosing another benefit package.

(1) *Participants.* Subject to paragraph (d)(3) of this section, a plan or issuer may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of participants is based on a bona fide employment-based classification consistent with the employer's usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to paragraph (d)(3) of this section, examples of classifications that, based on all the relevant facts and circumstances, may be bona fide include full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations. However, a classification based on any health factor is not a bona fide employment-based classification, unless the requirements of paragraph (g) of this section are satisfied (permitting favorable treatment of individuals with adverse health factors).

(2) *Beneficiaries*—(i) Subject to paragraph (d)(3) of this section, a plan or issuer may treat beneficiaries as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of beneficiaries is based on any of the following factors:

(A) A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage;

(B) Relationship to the participant (e.g., as a spouse or as a dependent child);

(C) Marital status;

(D) With respect to children of a participant, age or student status; or

(E) Any other factor if the factor is not a health factor.

(ii) Paragraph (d)(2)(i) of this section does not prevent more favorable treatment of individuals with adverse health factors in accordance with paragraph (g) of this section.

(3) *Discrimination directed at individuals.* Notwithstanding paragraphs (d)(1) and (2) of this section, if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries, the classification is not permitted under this paragraph (d), unless it is permitted under paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors). Thus, if an employer modified an employment-based classification to single out, based on a health factor, individual participants and beneficiaries and deny them health coverage, the new classification would not be permitted under this section.

(4) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the employer's ususal business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, treating the full-time and part-time employees as two separate groups of similarly situated individuals is permitted under this paragraph (d) because the classification is bona fide and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* Under a group health plan, coverage is made available to employees, their spouses, and their dependent children. However, coverage is made available to a dependent child only if the dependent child is under age 19 (or under age 25 if the child is continuously enrolled full-time in an institution of higher learning (full-time students)). There is no evidence to suggest that these classifications are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2*, treating spouses and dependent children differently by imposing an age limitation on dependent children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and dependent children is permitted under paragraph (d)(2) of this section and is not prohibited under paragraph (d)(3) of this section because it is not directed at individual participants or beneficiaries. It is also permissible to treat dependent children who are under age 19 (or full-time students under age 25) as a group of similarly situated individuals separate from those who are age 25 or older (or age 19 or older if they are not full-time students) because the classification is permitted under paragraph (d)(2) of this section and is not directed at individual participants or beneficiaries.

Example 3. (i) *Facts.* A university sponsors a group health plan that provides one health benefit package to faculty and another health benefit package to other staff. Faculty and staff are treated differently with respect to other employee benefits such as retirement benefits and leaves of absence. There is no evidence to suggest that the distinction is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 3*, the classification is permitted under this paragraph (d) because there is a distinction based on a bona fide employment-based classification consistent with the employer's usual business practice and the distinction is not directed at individual participants and beneficiaries.

Example 4. (i) *Facts.* An employer sponsors a group health plan that is available to all current employees. Former employees may also be eligible, but only if they complete a specified number of years of service, are enrolled under the plan at the time of termination of employment, and are continuously enrolled from that date. There is no evidence to suggest that these distinctions are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4*, imposing additional eligibility requirements on former employees is permitted because a classification that distinguishes between current and former employees is a bona fide employment-based classification that is permitted under this paragraph (d), provided that it is not directed at individual participants or beneficiaries. In addition, it is permissible to distinguish between former employees who satisfy the service requirement and those who do not, provided that the distinction is not directed at individual participants or beneficiaries. (However, former employees who do not satisfy the eligibility criteria may, nonetheless, be eligible for continued coverage pursuant to a COBRA continuation provision or similar State law.)

Example 5. (i) *Facts.* An employer sponsors a group health plan that provides the same benefit package to all seven employees of the employer. Six of the seven employees have the same job title and responsibilities, but Employee *G* has a different job title and different responsibilities. After *G* files an expensive claim for benefits under the plan, coverage under the plan is modified so that employees with *G*'s job title receive a different benefit package that includes a lower lifetime dollar limit than in the benefit package made available to the other six employees.

(ii) *Conclusion.* Under the facts of this *Example 5*, changing the coverage classification for *G* based on the existing employment classification for *G* is not permitted under this paragraph (d) because the creation of the new coverage classification for *G* is directed at *G* based on one or more health factors.

(e) *Nonconfinement and actively-at-work provisions*—(1) *Nonconfinement provisions*—(i) *General rule.* Under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is confined to a hospital or other health care institution. In addition, under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility or set any individual's premium or contribution rate based on an individual's ability to engage in normal life activities, except to the extent permitted under paragraphs (e)(2)(ii) and (3) of this section (permitting plans and issuers, under certain circumstances, to distinguish among employees based on the performance of services).

(ii) *Examples.* The rules of this paragraph (e)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, coverage for employees and their dependents generally becomes effective on the first day of employment. However, coverage for a dependent who is confined to a hospital or other health care institution does not become effective until the confinement ends.

(ii) *Conclusion.* In this *Example 1*, the plan violates this paragraph (e)(1) because the plan delays the effective date of coverage for dependents based on confinement to a hospital or other health care institution.

Example 2. (i) *Facts.* In previous years, a group health plan has provided coverage through a group health insurance policy offered by Issuer *M*. However, for the current year, the plan provides coverage through a group health insurance policy offered by Issuer *N*. Under Issuer *N*'s policy, items and services provided in connection with the confinement of a dependent to a hospital or other health care institution are not covered if the confinement is covered under an extension of benefits clause from a previous health insurance issuer.

(ii) *Conclusion.* In this *Example 2*, Issuer *N* violates this paragraph (e)(1) because the group health insurance coverage restricts benefits (a rule for eligibility under paragraph (b)(1)) based on whether a dependent is confined to a hospital or other health care institution that is covered under an extension of benefits clause from a previous issuer. This section does not affect any obligation Issuer *M* may have under applicable State law to provide any extension of benefits and does not affect any State law governing coordination of benefits.

(2) *Actively-at-work and continuous service provisions*—(i) *General rule*—(A) Under the rules of paragraphs (b) and (c) of this section and subject to the exception for the first day of work described in paragraph (e)(2)(ii) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor (such as being absent from work on sick leave) is treated, for purposes of the plan or health insurance coverage, as being actively at work.

(B) The rules of this paragraph (e)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, an employee generally becomes eligible to enroll 30 days after the first day of employment. However, if the employee is not actively at work on the first day after the end of the 30-day period, then eligibility for enrollment is delayed until the first day the employee is actively at work.

(ii) *Conclusion.* In this *Example 1*, the plan violates this paragraph (e)(2) (and thus also violates paragraph (b) of this section). However, the plan would not violate paragraph (e)(2) or (b) of this section if, under the plan, an absence due to any health factor is considered being actively at work.

Example 2. (i) *Facts.* Under a group health plan, coverage for an employee becomes effective after 90 days of continuous service; that is, if an employee is absent from work (for any reason) before completing 90 days of service, the beginning of the 90-day period is measured from the day the employee returns to work (without any credit for service before the absence).

(ii) *Conclusion.* In this *Example 2,* the plan violates this paragraph (e)(2) (and thus also paragraph (b) of this section) because the 90-day continuous service requirement is a rule for eligibility based on whether an individual is actively at work. However, the plan would not violate this paragraph (e)(2) or paragraph (b) of this section if, under the plan, an absence due to any health factor is not considered an absence for purposes of measuring 90 days of continuous service.

(ii) *Exception for the first day of work*—(A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan or issuer may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

(B) The rules of this paragraph (e)(2)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Under the eligibility provision of a group health plan, coverage for new employees becomes effective on the first day that the employee reports to work. Individual *H* is scheduled to begin work on August 3. However, *H* is unable to begin work on that day because of illness. *H* begins working on August 4, and *H*'s coverage is effective on August 4.

(ii) *Conclusion.* In this *Example 1*, the plan provision does not violate this section. However, if coverage for individuals who do not report to work on the first day they were scheduled to work for a reason unrelated to a health factor (such as vacation or bereavement) becomes effective on the first day they were scheduled to work, then the plan would violate this section.

Example 2. (i) *Facts.* Under a group health plan, coverage for new employees becomes effective on the first day of the month following the employee's first day of work, regardless of whether the employee is actively at work on the first day of the month. Individual *J* is scheduled to begin work on March 24. However, *J* is unable to begin work on March 24 because of illness. *J* begins working on April 7 and *J*'s coverage is effective May 1.

(ii) *Conclusion.* In this *Example 2*, the plan provision does not violate this section. However, as in *Example 1*, if coverage for individuals absent from work for reasons unrelated to a health factor became effective despite their absence, then the plan would violate this section.

(3) *Relationship to plan provisions defining similarly situated individuals*—(i) Notwithstanding the rules of paragraphs (e)(1) and (2) of this section, a plan or issuer may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in paragraph (d) of this section. Accordingly, a plan or issuer may distinguish in rules for eligibility under the plan between full-time and part-time employees, between permanent and temporary or seasonal employees, between current and former employees, and between employees currently performing services and employees no longer performing services for the employer, subject to paragraph (d) of this section. However, other federal or

State laws (including the COBRA continuation provisions and the Family and Medical Leave Act of 1993) may require an employee or the employee's dependents to be offered coverage and set limits on the premium or contribution rate even though the employee is not performing services.

(ii) The rules of this paragraph (e)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, employees are eligible for coverage if they perform services for the employer for 30 or more hours per week or if they are on paid leave (such as vacation, sick, or bereavement leave). Employees on unpaid leave are treated as a separate group of similarly situated individuals in accordance with the rules of paragraph (d) of this section.

(ii) *Conclusion.* In this *Example 1,* the plan provisions do not violate this section. However, if the plan treated individuals performing services for the employer for 30 or more hours per week, individuals on vacation leave, and individuals on bereavement leave as a group of similarly situated individuals separate from individuals on sick leave, the plan would violate this paragraph (e) (and thus also would violate paragraph (b) of this section) because groups of similarly situated individuals cannot be established based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

Example 2. (i) *Facts.* To be eligible for coverage under a bona fide collectively bargained group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the three-month period that ends one month before the beginning of the current calendar quarter. The distinction between employees working at least 250 hours and those working less than 250 hours in the earlier three-month period is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2,* the plan provision does not violate this section because, under the rules for similarly situated individuals allowing full-time employees to be treated differently than part-time employees, employees who work at least 250 hours in a three-month period can be treated differently than employees who fail to work 250 hours in that period. The result would be the same if the plan permitted individuals to apply excess hours from previous periods to satisfy the requirement for the current quarter.

Example 3. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee *B* has been covered under the plan. *B* experiences a disabling illness that prevents *B* from working. *B* takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, *B* terminates employment and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 3,* the plan provision terminating *B*'s coverage upon *B*'s termination of employment does not violate this section.

Example 4. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the employee ceases to perform services for the employer sponsoring the plan, in accordance with the rules of paragraph (d) of this section. Employee *C* is laid off for three months. When the layoff begins, *C*'s coverage under the plan is terminated. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 4,* the plan provision terminating *C*'s coverage upon the cessation of *C*'s performance of services does not violate this section.

(f) *Bona fide wellness programs.* [Reserved.]

(g) *More favorable treatment of individuals with adverse health factors permitted*—(1) *In rules for eligibility*—(i) Nothing in this section prevents a group health plan or group health insurance issuer from establishing more favorable rules for eligibility (described in paragraph (b)(1) of this section) for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor. Moreover, nothing in this section prevents a plan or issuer from charging a higher premium or contribution with respect to individuals with an adverse health factor if they would not be eligible for the coverage were it not for the adverse health factor. (However, other laws, including State insurance laws, may set or limit premium rates; these laws are not affected by this section.)

(ii) The rules of this paragraph (g)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that generally is available to employees, spouses of employees, and dependent children until age 23. However, dependent children who are disabled are eligible for coverage beyond age 23.

(ii) *Conclusion.* In this *Example 1,* the plan provision allowing coverage for disabled dependent children beyond age 23 satisfies this paragraph (g)(1) (and thus does not violate this section).

Example 2. (i) *Facts.* An employer sponsors a group health plan, which is generally available to employees (and members of the employee's family) until the last day of the month in which the employee ceases to perform services for the employer. The plan generally charges employees $50 per month for employee-only coverage and $125 per month for family coverage. However, an employee who ceases to perform services for the employer by reason of disability may remain covered under the plan until the last day of the month that is 12 months after the month in which the employee ceased to perform services for the employer. During this extended period of coverage, the plan charges the employee $100 per month for employee-only coverage and $250 per month for family coverage. (This extended period of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 2,* the plan provision allowing extended coverage for disabled employees and their families satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled employees a higher premium during the extended period of coverage.

Example 3. (i) *Facts.* To comply with the requirements of a COBRA continuation provision, a group health plan generally makes COBRA continuation coverage available for a maximum period of 18 months in connection with a termination of employment but makes the coverage available for a maximum period of 29 months to certain disabled individuals and certain members of the disabled individual's family. Although the plan generally requires payment of 102 percent of the applicable premium for the first 18 months of COBRA continuation coverage, the plan requires payment of 150 percent of the applicable premium for the disabled individual's COBRA continuation coverage during the disability extension if the disabled individual would not be entitled to COBRA continuation coverage but for the disability.

(ii) *Conclusion.* In this *Example 3,* the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)

(2) *In premiums or contributions*—(i) Nothing in this section prevents a group health plan or group health insurance issuer from charging individuals a premium or contribution that is less than the premium (or contribution) for similarly situated individuals if the lower charge is based on an adverse health factor, such as disability.

(ii) The rules of this paragraph (g)(2) are illustrated by the following example:

Example. (i) *Facts.* Under a group health plan, employees are generally required to pay $50 per month for employee-only coverage and $125 per month for family coverage

under the plan. However, employees who are disabled receive coverage (whether employee-only or family coverage) under the plan free of charge.

(ii) *Conclusion.* In this *Example,* the plan provision waiving premium payment for disabled employees is permitted under this paragraph (g)(2) (and thus does not violate this section).

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of the PHS Act (including the COBRA continuation provisions) or any other State or federal law, such as the Americans with Disabilities Act. Therefore, although the rules of this section would not prohibit a plan or issuer from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans and issuers, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.

(*i*) *Applicability dates*—(1) *Paragraphs applicable March 9, 2001.* Paragraphs (a)(1), (a)(2)(i), (b)(1)(i), (b)(1)(iii) *Example 1,* (b)(2)(i)(A), (b)(2)(ii), (c)(1)(i), (c)(2)(i), and (c)(3) of this section and this paragraph (*i*)(1) apply to group health plans and health insurance issuers offering group health insurance coverage March 9, 2001.

(2) *Paragraphs applicable for plan years beginning on or after July 1, 2001.* Except as provided in paragraph (*i*)(3) or (*i*)(4) of this section, the provisions of this section not listed in paragraph (*i*)(1) of this section apply to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after July 1, 2001. Except as provided in paragraph (*i*)(3) or (*i*)(4) of this section, with respect to efforts to comply with section 2702 of the PHS Act before the first plan year beginning on or after July 1, 2001, the Secretary will not take any enforcement action against an issuer or plan that has sought to comply in good faith with section 2702 of the PHS Act.

(3) *Transitional rules for individuals previously denied coverage based on a health factor.* This paragraph (*i*)(3) provides rules relating to individuals previously denied coverage under a group health plan or group health insurance coverage based on a health factor of the individual. Paragraph (*i*)(3)(i) clarifies what constitutes a denial of coverage under this paragraph (*i*)(3). Paragraph (*i*)(3)(ii) of this section applies with respect to any individual who was denied coverage if the denial was not based on a good faith interpretation of section 2702 of the PHS Act or the Secretary's published guidance. Under that paragraph, such an individual must be allowed to enroll retroactively to the effective date of section 2702 of the PHS Act, or, if later, the date the individual meets eligibility criteria under the plan that do not discriminate based on any health factor. Paragraph (*i*)(3)(iii) of this section applies with respect to any individual who was denied coverage based on a good faith interpretation of section 2702 of the PHS Act or the Secretary's published guidance. Under that paragraph, such an individual must be given an opportunity to enroll effective July 1, 2001. In either event, whether under paragraph (*i*)(3)(ii) or (iii) of this section, the Secretary will not take any enforcement action with respect to denials of coverage addressed in this paragraph (*i*)(3) if the issuer or plan has complied with the transitional rules of this paragraph (*i*)(3).

(i) *Denial of coverage clarified.* For purposes of this paragraph (*i*)(3), an individual is considered to have been denied coverage if the individual—

(A) Failed to apply for coverage because it was reasonable to believe that an application for coverage would have been futile due to a plan provision that discriminated based on a health factor; or

(B) Was not offered an opportunity to enroll in the plan and the failure to give such an opportunity violates this section.

(ii) *Individuals denied coverage without a good faith interpretation of the law*—(A) *Opportunity to enroll required.* If a plan or issuer has denied coverage to any individual based on a health factor and that denial was not based on a good faith interpretation of section 2702 of the PHS Act or any guidance published by the Secretary, the plan or issuer is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days. This opportunity must be presented not later than March 9, 2001.

(*1*) If this enrollment opportunity was presented before or within the first plan year beginning on or after July 1, 1997 (or in the case of a collectively bargained plan, before or within the first plan year beginning on the effective date for the plan described in section 102(c)(3) of the Health Insurance Portability and Accountability Act of 1996), the coverage must be effective within that first plan year.

(*2*) If this enrollment opportunity is presented after such plan year, the individual must be given the choice of having the coverage effective on either of the following two dates—

(*i*) The date the plan receives a request for enrollment in connection with the enrollment opportunity; or

(*ii*) Retroactively to the first day of the first plan year beginning on the effective date for the plan described in sections 102(c)(1) and (3) of the Health Insurance Portability and Accountability Act of 1996 (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). If an individual elects retroactive coverage, the plan or issuer is required to provide the benefits it would have provided if the individual had been enrolled for coverage during that period (irrespective of any otherwise applicable plan provisions governing timing for the submission of claims). The plan or issuer may require the individual to pay whatever additional amount the individual would have been required to pay for the coverage (but the plan or issuer cannot charge interest on that amount).

(B) *Relation to preexisting condition rules.* For purposes of section 2701 of the PHS Act, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date is the effective date for the plan described in sections 102(c)(1) and (3) of the Health Insurance Portability and Accountability Act (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan), even if the individual chooses under paragraph (*i*)(3)(ii)(A) of this section to have coverage effective only prospectively. In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

(C) *Examples.* The rules of this paragraph (*i*)(3)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *X* maintains a group health plan with a plan year beginning October 1 and ending September 30. Individual *F* was hired by Employer *X* before the effective date of section 2702 of the PHS Act. Before the effective date of section 2702 of the PHS Act for this plan (October 1, 1997), the terms of the plan allowed employees and their dependents to enroll when the employee was first hired,

and on each January 1 thereafter, but in either case, only if the individual could pass a physical examination. *F*'s application to enroll when first hired was denied because *F* had diabetes and could not pass a physical examination. Upon the effective date of section 2702 of the PHS Act for this plan (October 1, 1997), the plan is amended to delete the requirement to pass a physical examination. In November of 1997, the plan gives *F* an opportunity to enroll in the plan (including notice of the opportunity to enroll) without passing a physical examination, with coverage effective January 1, 1998.

(ii) *Conclusion.* In this *Example 1,* the plan complies with the requirements of this paragraph (*i*)(3)(ii).

Example 2. (i) *Facts.* The plan year of a group health plan begins January 1 and ends December 31. Under the plan, a dependent who is unable to engage in normal life activities on the date coverage would otherwise become effective is not enrolled until the dependent is able to engage in normal life activities. Individual *G* is a dependent who is otherwise eligible for coverage, but is unable to engage in normal life activities. The plan has not allowed *G* to enroll for coverage.

(ii) *Conclusion.* In this *Example 2,* beginning on the effective date of section 2702 of the PHS Act for the plan (January 1, 1998), the plan provision is not permitted under any good faith interpretation of section 2702 of the PHS Act or any guidance published by the Secretary. Therefore, the plan is required, not later than March 9, 2001, to give *G* an opportunity to enroll (including notice of the opportunity to enroll), with coverage effective, at *G*'s option, either retroactively from January 1, 1998 or prospectively from the date *G*'s request for enrollment is received by the plan. If *G* elects coverage to be effective beginning January 1, 1998, the plan can require *G* to pay any required employee premiums for the retroactive coverage.

(iii) *Individuals denied coverage based on a good faith interpretation of the law*—(A) *Opportunity to enroll required.* If a plan or issuer has denied coverage to any individual before the first day of the first plan year beginning on or after July 1, 2001 based in part on a health factor and that denial was based on a good faith interpretation of section 2702 of the PHS Act or guidance published by the Secretary, the plan or issuer is required to give the individual an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, with coverage effective no later than July 1, 2001. Individuals required to be offered an opportunity to enroll include individuals previously offered enrollment without regard to a health factor but subsequently denied enrollment due to a health factor.

(B) *Relation to preexisting condition rules.* For purposes of section 2701 of the PHS Act, the individual may not be treated as a late enrollee or as a special enrollee. Moreover, the individual's enrollment date is the effective date for the plan described in sections 102(c)(1) and (3) of the Health Insurance Portability and Accountability Act (or, if the individual otherwise first became eligible to enroll for coverage after that date, on the date the individual was otherwise eligible to enroll in the plan). In addition, any period between the individual's enrollment date and the effective date of coverage is treated as a waiting period.

(C) *Example.* The rules of this paragraph (i)(3)(iii) are illustrated by the following example:

Example. (i) *Facts.* Individual *H* was hired by Employer *Y* on May 3, 1995. *Y* maintains a group health plan with a plan year beginning on February 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired (without a requirement to pass a physical examination), and on each February 1 thereafter if the individual can pass a physical examination. *H* chose not to enroll for coverage when hired in May of 1995. On February 1, 1997, *H* tried to enroll for coverage under the plan. However, *H* was denied coverage for failure to pass a physical examination. Shortly thereafter, *Y*'s plan eliminated late enrollment, and *H* was not given another opportunity to enroll in the plan. There is no evidence to suggest that *Y*'s plan was acting in bad faith in denying coverage under the plan beginning on the effective date of section 2702 of the PHS Act (February 1, 1998).

(ii) *Conclusion.* In this *Example,* because coverage previously had been made available with respect to *H* without regard to any health factor of *H* and because *Y*'s plan was acting in accordance with a good faith interpretation of section 2702 of the PHS Act (and guidance published by the Secretary), the failure of *Y*'s plan to allow *H* to enroll effective February 1, 1998 was permissible on that date. However, under the transitional rules of this paragraph (i)(3)(iii), *Y*'s plan must give *H* an opportunity to enroll that continues for at least 30 days, with coverage effective no later than July 1, 2001. (In addition, February 1, 1998 is *H*'s enrollment date under the plan and the period between February 1, 1998 and July 1, 2001 is treated as a waiting period. Accordingly, any preexisting condition exclusion period permitted under § 146.111 will have expired before July 1, 2001.)

(4) *Special transitional rule for self-funded non-Federal governmental plans exempted under 45 CFR 146.180*—(i) If coverage has been denied to any individual because the sponsor of a self-funded non-Federal governmental plan has elected under § 146.180 to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan—

(A) Must notify the individual that the plan will be coming into compliance with the requirements of this section, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a matter of administrative convenience, the notice may be disseminated to all employees);

(B) Must give the individual an opportunity to enroll that continues for at least 30 days;

(C) Must permit coverage to be effective as of the first day of plan coverage for which an exemption election under § 146.180 (with regard to this section) is no longer in effect (or July 1, 2001, if later, and the plan was acting in accordance with a good faith interpretation of section 2702 of the PHS Act and guidance published by HCFA); and

(D) May not treat the individual as a late enrollee or a special enrollee.

(ii) For purposes of this paragraph (i)(4), an individual is considered to have been denied coverage if the individual failed to apply for coverage because, given an exemption election under § 146.180, it was reasonable to believe that an application for coverage would have been denied based on a health factor.

(iii) The rules of this paragraph (i)(4) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *D* was hired by a non-Federal governmental employer in June 1996. The employer maintains a self-funded group health plan with a plan year beginning on October 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual may enroll effective October 1 of any plan year if the individual can pass a physical examination. The plan sponsor elected under § 146.180 of this part to exempt the plan from the requirements of this section for the plan year beginning October 1, 1997, and renewed the exemption election for the plan year beginning October 1, 1998. That is, the plan sponsor elected to retain the evidence of good health requirement for late enrollees which, absent an exemption election under § 146.180 of this part, would have been in violation of this section as of October 1, 1997. *D* chose not to enroll for coverage when first hired. In February of 1998, *D* was treated for skin cancer but did not apply for coverage under the plan for the plan year beginning October 1, 1998, because *D* assumed *D* could not meet the evidence of good health requirement. With the plan year beginning October 1, 1999, the plan sponsor chose not to renew its exemption election and brought the plan into compliance with this section. However, the terms of the plan, effective

October 1, 1999, were amended to permit enrollment only during the initial 30-day period of employment. The plan no longer permits late enrollment under any circumstances, including with respect to current employees not enrolled in the plan. Therefore, *D* was not given another opportunity to enroll in the plan. There is no evidence to suggest that the plan was acting in bad faith in denying *D* coverage under the plan beginning on the effective date of § 146.121 for the plan (October 1, 1999).

(ii) *Conclusion.* In this *Example 1*, because the plan under § 146.180 was previously excluded from the requirements of § 146.121 and thereafter was acting in accordance with a good faith interpretation of § 146.121 and guidance published by HCFA, the failure of the plan to give *D* an opportunity to enroll effective October 1, 1999 was permissible on that date. However, under the transitional rules of this paragraph (i)(4), the plan must give *D* an opportunity to enroll that continues for at least 30 days, with coverage effective no later than July 1, 2001. (Additionally, October 1, 1999 is *D*'s enrollment date under the plan and the period between October 1, 1999 and July 1, 2001 is treated as a waiting period. Furthermore, if the plan sponsor has not elected to exempt the plan from limitations on preexisting condition exclusion periods, any preexisting condition exclusion period must be administered in accordance with § 146.111. Accordingly, any preexisting condition exclusion period permitted under § 146.111 will have expired before July 1, 2001.)

Example 2. (i) *Facts.* Individual *E* was hired by a non-Federal governmental employer in February 1995. The employer maintains a self-funded group health plan with a plan year beginning on September 1. Under the terms of the plan, employees and their dependents are allowed to enroll when the employee is first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual may enroll effective September 1 of any plan year if the individual can pass a physical examination. All enrollees are subject to a 12-month preexisting condition exclusion period. The plan sponsor elected under § 146.180 of this part to exempt the plan from the requirements of this section and § 146.111 (limitations on preexisting condition exclusion periods) for the plan year beginning September 1, 1997, and renews the exemption election for the plan years beginning September 1, 1998, September 1, 1999, and September 1, 2000. *E* chose not to enroll for coverage when first hired. In June of 2001, *E* is diagnosed as having multiple sclerosis (MS). With the plan year beginning September 1, 2001, the plan sponsor chooses to bring the plan into compliance with this section, but renews its exemption election with regard to limitations on preexisting condition exclusion periods. The plan affords *E* an opportunity to enroll, without a physical examination, effective September 1, 2001. *E* is subject to a 12-month preexisting condition exclusion period with respect to any treatment *E* receives that is related to *E*'s MS, without regard to any prior creditable coverage *E* may have. Beginning September 1, 2002, the plan will cover treatment of *E*'s MS.

(ii) *Conclusion.* In this *Example 2,* the plan complies with the requirements of this section. (The plan is not required to comply with the requirements of § 146.111 because the plan continues to be exempted from those requirements in accordance with the plan sponsor's election under § 146.180.)

3. The heading, paragraph (a)(1), and the first sentence of paragraph (a)(2) of § 146.125 are revised to read as follows:

§ 146.125 Applicability dates.

(a) *General applicability dates*—(1) *Non-collectively bargained plans.* Part A of title XXVII of the PHS Act and §§ 146.101 through 146.119, § 146.143, § 146.145, 45 CFR part 150, and this section apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997, except as otherwise provided in this section.

(2) *Collectively-bargained plans.* Except as otherwise provided in this section (other than paragraph (a)(1) of this section), in the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before August 21, 1996, Part A of Title XXVII of the PHS Act and §§ 146.101 through 146.119, § 146.143, § 146.145, 45 CFR part 150, and this section do not apply to plan years beginning before the later of July 1, 1997, or the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after August 21, 1996). * * *

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Dated: June 22, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: August 29, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 01–106 Filed 1–5–01; 8:45 am]

BILLING CODE 4120–01–P; 4830–01–P; 4510–29–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–114084–00]

RIN 1545–AY34

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2590

RIN 1210–AA77

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

45 CFR Part 146

RIN 0938–AK19

Notice of Proposed Rulemaking for Bona Fide Wellness Programs

AGENCIES: Internal Revenue Service, Department of the Treasury; Pension and Welfare Benefits Administration, Department of Labor; Health Care Financing Administration, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: This proposed rule would implement and clarify the term ''bona fide wellness program'' as it relates to regulations implementing the nondiscrimination provisions of the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act, as added by the Health Insurance Portability and Accountability Act of 1996.

DATES: Written comments on this notice of proposed rulemaking are invited and must be received by the Departments on or before April 9, 2001.

ADDRESSES: Written comments should be submitted with a signed original and three copies (except for electronic submissions to the Internal Revenue Service (IRS) or Department of Labor) to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments.

Comments to the IRS can be addressed to: CC:M&SP:RU (REG–114084–00), Room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044.

In the alternative, comments may be hand-delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–114084–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224.

Alternatively, comments may be transmitted electronically via the IRS Internet site at: *http://www.irs.gov/tax_regs/regslist.html.*

Comments to the Department of Labor can be addressed to: U.S. Department of Labor Pension and Welfare Benefits Administration, 200 Constitution Avenue NW., Room C–5331, Washington, DC 20210, *Attention:* Wellness Program Comments.

Alternatively, comments may be hand-delivered between the hours of 9 a.m. and 5 p.m. to the same address. Comments may also be transmitted by e-mail to: Wellness@pwba.dol.gov.

Comments to HHS can be addressed to: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2078–P, P.O. Box 26688, Baltimore, MD 21207.

In the alternative, comments may be hand-delivered between the hours of 8:30 a.m. and 5 p.m. to either:

Room 443–G, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

All submissions to the Department of Labor will be open to public inspection and copying in the Public Documents Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue, NW., Washington, DC from 8:30 a.m. to 5:30 p.m.

All submissions to HHS will be open to public inspection and copying in room 309–G of the Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC from 8:30 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Amy J. Turner, Pension and Welfare Benefits Administration, Department of Labor, at (202) 219–4377; or Ruth A. Bradford, Health Care Financing Administration, Department of Health and Human Services, at (410) 786–1565.

SUPPLEMENTARY INFORMATION:

Customer Service Information

Individuals interested in obtaining additional information on HIPAA's nondiscrimination rules may request a copy of the Department of Labor's booklet entitled ''Questions and Answers: Recent Changes in Health Care Law'' by calling the PWBA Toll-Free Publication Hotline at 1–800–998–7542 or may request a copy of the Health Care Financing Administration's new publication entitled ''Protecting Your Health Insurance Coverage'' by calling (410) 786–1565. Information on HIPAA's nondiscrimination rules and other recent health care laws is also available on the Department of Labor's website (http://www.dol.gov/dol/pwba) and the Department of Health and Human Services' website (http://hipaa.hcfa.gov).

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, was enacted on August 21, 1996. HIPAA amended the Internal Revenue Code of 1986 (Code), the Employee Retirement Income Security Act of 1974 (ERISA), and the Public Health Service Act (PHS Act) to provide for, among other things, improved portability and continuity of health coverage. HIPAA added section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act, which prohibit discrimination in health coverage. However, the HIPAA nondiscrimination provisions do not prevent a plan or issuer from establishing discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention. Interim final rules implementing the HIPAA provisions were first made available to the public on April 1, 1997 (published in the **Federal Register** on April 8, 1997, 62 FR 16894) (April 1997 interim rules).

In the preamble to the April 1997 interim rules, the Departments invited comments on whether additional guidance was needed concerning, among other things, the permissible standards for determining bona fide wellness programs. The Departments also stated that they intend to issue further regulations on the nondiscrimination rules and that in no event would the Departments take any enforcement action against a plan or issuer that had sought to comply in good faith with section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act before the additional guidance is provided. The new interim regulations relating to the HIPAA nondiscrimination rules (published elsewhere in this issue of the

Federal Register) do not include provisions relating to bona fide wellness programs. Accordingly, the period for good faith compliance continues with respect to those provisions until further guidance is issued. Compliance with the provisions of these proposed regulations constitutes good faith compliance with the statutory provisions relating to wellness programs.

II. Overview of the Proposed Regulations

The HIPAA nondiscrimination provisions generally prohibit a plan or issuer from charging similarly situated individuals different premiums or contributions based on a health factor. In addition, under the interim regulations published elsewhere in this issue of the **Federal Register**, cost-sharing mechanisms such as deductibles, copayments, and coinsurance are considered restrictions on benefits. Thus, they are subject to the same rules as are other restrictions on benefits; that is, they must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. However, the HIPAA nondiscrimination provisions do not prevent a plan or issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention. Thus, there is an exception to the general rule prohibiting discrimination based on a health factor if the reward, such as a premium discount or waiver of a cost-sharing requirement, is based on participation in a program of health promotion or disease prevention. The April 1997 interim rules, the interim regulations published elsewhere in this issue of the **Federal Register**, and these proposed regulations refer to programs of health promotion and disease prevention allowed under this exception as ''bona fide wellness programs.'' In order to prevent the exception to the nondiscrimination requirements for bona fide wellness programs from eviscerating the general rule contained in the HIPAA nondiscrimination provisions, these proposed regulations impose certain requirements on wellness programs providing rewards that would otherwise discriminate based on a health factor.

A wide range of wellness programs exist to promote health and prevent disease. However, many of these programs are not subject to the bona fide wellness program requirements. The requirements for bona fide wellness programs apply only to a wellness program that provides a reward based on the ability of an individual to meet a standard that is related to a health factor, such as a reward conditioned on the outcome of a cholesterol test. Therefore, without having to comply with the requirements for a bona fide wellness program, a wellness program could—

- Provide voluntary testing of enrollees for specific health problems and make recommendations to address health problems identified, if the program did not base any reward on the outcome of the health assessment;
- Encourage preventive care through the waiver of the copayment or deductible requirement for the costs of well-baby visits;
- Reimburse employees for the cost of health club memberships, without regard to any health factors relating to the employees; or
- Reimburse employees for the costs of smoking cessation programs, without regard to whether the employee quits smoking.

A wellness program that provides a reward based on the ability of an individual to meet a standard related to a health factor violates the interim regulations published elsewhere in this issue of the **Federal Register** unless it is a bona fide wellness program. Under these proposed regulations, a wellness program must meet four requirements to be a bona fide wellness program.

First, the total reward that may be given to an individual under the plan for all wellness programs is limited. A reward can be in the form of a discount, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge. The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed a specified percentage of the cost of employee-only coverage under the plan. The cost of employee-only coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is receiving coverage.

The proposed regulations specify three alternative percentages: 10, 15, and 20. The Departments welcome comments on the appropriate level for the percentage. Comments will be taken into account in determining the standard for the final regulations.

Several commenters on the April 1997 regulations suggested that the amount of a reward should be permitted if it is actuarially determined based on the costs associated with the health factor measured under the wellness program. However, in some cases, the resulting reward (or penalty) might be so large as to have the effect of denying coverage to certain individuals. The percentage limitation in the proposed regulations is designed to avoid this result. The percentage limitation also avoids the additional administrative costs of a reward based on actuarial cost.

The Departments recognize that there may be some programs that currently offer rewards, individually or in the aggregate, that exceed the specified percentage. However, as noted below in the economic analysis, data is scarce regarding practices of wellness programs. Thus, the Departments specifically request comments on the appropriateness of the specified percentage of the cost of employee-only coverage under a plan as the maximum reward for a bona fide wellness program, including whether a larger amount should be allowed for wellness programs that include participation by family members (*i.e.,* the specified percentage of the cost of family coverage). Note also that, as stated above, the period for good faith compliance continues with respect to whether wellness programs satisfy the statutory requirements. While compliance with these proposed regulations constitutes good faith compliance with the statutory provisions, it is possible that, based on all the facts and circumstances, a plan's wellness program that provides a reward in excess of the specified range of percentages of the cost of employee-only coverage may also be found to meet the good faith compliance standard.

Under these proposed regulations, the second requirement to be a bona fide wellness program is that the program must be reasonably designed to promote good health or prevent disease for individuals in the program. This requirement prevents a program from being a subterfuge for merely imposing higher costs on individuals based on a health factor by requiring a reasonable connection between the standard required under the program and the promotion of good health and disease prevention. Among other things, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year. In contrast, a program that imposes a

reward or penalty for the duration of the individual's participation in the plan based solely on health factors present when an individual first enrolls in a plan is not reasonably designed to promote health or prevent disease (because, if the individual cannot qualify for the reward by adopting healthier behavior after initial enrollment, the program does not have any connection to improving health).

The third requirement to be a bona fide wellness program under these proposed regulations is that the reward under the program must be available to all similarly situated individuals. The April 1997 interim rules provided that if, under the design of the wellness program, enrollees might not be able to achieve a program standard due to a health factor, the program would not be a bona fide wellness program. These proposed regulations increase flexibility for plans by allowing plans to make individualized adjustments to their wellness programs to address the health factors of the particular individuals for whom it is unreasonably difficult to qualify for the benefits under the program. Specifically, the program must allow any individual for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to satisfy the initial program standard an opportunity to satisfy a reasonable alternative standard. The examples clarify that a reasonable alternative standard must take into account the relevant health factor of the individual who needs the alternative. A program does not need to establish the specific reasonable alternative standard before the program commences. To satisfy this third requirement for being a bona fide wellness program, it is sufficient to determine a reasonable alternative standard once a participant informs the plan that it is unreasonably difficult for the participant due to a medical condition to satisfy the general standard (or that it is medically inadvisable for the participant to attempt to achieve the general standard) under the program.

Many commenters asked how the bona fide wellness program requirements apply to programs that provide a reward for not smoking. An example in the proposed regulations clarifies that if it is unreasonably difficult for an individual to stop smoking due to an addiction to nicotine,[1] the individual must be provided a reasonable alternative standard to obtain the reward.

The fourth requirement to be a bona fide wellness program under the proposed regulations is that all plan materials describing the terms of the program must disclose the availability of a reasonable alternative standard. The proposed regulations include model language that can be used to satisfy this requirement; examples also illustrate substantially similar language that would satisfy the requirement.

The proposed regulations contain two clarifications of this fourth requirement. First, plan materials are not required to describe specific reasonable alternative standards. It is sufficient to disclose that some reasonable alternative standard will be made available. Second, any plan materials that describe the general standard would also have to disclose the availability of a reasonable alternative standard. However, if the program is merely mentioned (and does not describe the general standard), disclosure of the availability of a reasonable alternative standard is not required.

III. Economic Impact and Paperwork Burden

Summary—Department of Labor and Department of Health and Human Services

Under the proposed regulation, health plans generally may vary employee premium contributions or benefit levels across similarly situated individuals based on health status factors only in connection with bona fide wellness programs. The regulation establishes four requirements for such bona fide wellness programs. It (1) limits the permissible amount of variation in employee premium or benefit levels; (2) requires that programs be reasonably designed to promote health or prevent disease; (3) requires programs to permit plan participants who for medical reasons would incur unreasonable difficulty to satisfy the programs' initial wellness standards to satisfy reasonable alternative standards instead; and (4) requires certain plan materials to disclose the availability of such alternative standards. The Departments carefully considered the costs and benefits attendant to these requirements. The Departments believe that the benefits of these requirements exceed their costs.

The Departments anticipate that the proposed regulation will result in transfers of cost among plan sponsors and participants and in new economic costs and benefits.

Economic benefits will flow from plan sponsors' efforts to maintain wellness programs' effectiveness where discounts or surcharges are reduced and from plans sponsors' provision of reasonable alternative standards that help improve affected plan participants' health habits and health. The result will be fewer instances where wellness programs merely shift costs to high risk individuals and more instances where they succeed at improving such individuals' health habits and health.

Transfers will arise because the size of some discounts and surcharges will be reduced, and because some plan participants who did not satisfy wellness programs' initial standards will satisfy alternative standards. These transfers are estimated to total between $18 million and $46 million annually. (The latter figure is an upper bound, reflecting the case in which all eligible participants pursue and satisfy alternative standards.)

New economic costs may be incurred if reductions in discounts or surcharges reduce wellness programs' effectiveness, but this effect is expected to be very small because reductions will be small and relatively few plans and participants will be affected. Other new economic costs will be incurred by plan sponsors to make available reasonable alternative standards where required. The Departments were unable to estimate these costs but are confident that these costs in combination with the transfers referenced above will not exceed the estimate of the transfers alone. Affected plan sponsors can satisfy the proposed regulation's third requirement by making available any reasonable standard they choose, including low cost alternatives. It is unlikely that plan sponsors would choose alternative standards whose cost, in combination with costs transferred from participants who satisfy them, would exceed the cost of providing discounts or waiving surcharges for all eligible participants.

Executive Order 12866—Department of Labor and Department of Health and Human Services

Under Executive Order 12866, the Departments must determine whether a regulatory action is ''significant'' and therefore subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million

[1] Under the *Diagnostic and Statistical Manual of Mental Disorders,* Fourth Edition, American Psychiatric Association, 1994 (DSM IV), nicotine addiction is a medical condition. See also Rev. Rul. 99–28, 1999–25 I.R.B. 6 (June 21, 1999), citing a report of the Surgeon General stating that scientists in the field of drug addiction agree that nicotine, a substance common to all forms of tobacco, is a powerfully addictive drug.

or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising 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 the Executive Order, it has been determined that this action raises novel policy issues arising out of legal mandates. Therefore, this notice is ''significant'' and subject to OMB review under Section 3(f)(4) of the Executive Order. Consistent with the Executive Order, the Departments have assessed the costs and benefits of this regulatory action. The Departments' assessment, and the analysis underlying that assessment, is detailed below. The Departments performed a comprehensive, unified analysis to estimate the costs and benefits attributable to the interim regulation for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act.

Statement of Need for Proposed Action

These interim regulations are needed to clarify and interpret the HIPAA nondiscrimination provisions (Prohibiting Discrimination Against Individual Participants and Beneficiaries Based on Health Status) under Section 702 of the Employee Retirement Income Security Act of 1974 (ERISA), Section 2702 of the Public Health Service Act, and Section 9802 of the Internal Revenue Code of 1986. The provisions are needed to ensure that group health plans and group health insurers and issuers do not discriminate against individuals, participants, and beneficiaries based on any health factors with respect to health care premiums. Additional guidance was required to define bona fide wellness programs.

Costs and Benefits

The Departments anticipate that the proposed regulation will result in transfers of cost among plans sponsors and participants and in new economic costs and benefits. The economic benefits of the regulation will include a reduction in instances where wellness programs merely shift costs to high risk individuals and an increase in instances where they succeed at improving such individuals' health habits and health. Transfers are estimated to total between $18 million and $46 million annually. The Departments were unable to estimate new economic costs but are confident that these costs in combination with the transfers referenced above will not exceed the estimate of the transfers alone. The Departments believe that the regulation's benefits will exceed its costs. Their unified analysis of the regulation's costs and benefits is detailed later in this preamble.

Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires that the agency present an initial regulatory flexibility analysis (IRFA) at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations and governmental jurisdictions.

For purposes of analysis under the RFA, PWBA proposes to continue to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of the Employee Retirement Income Security Act of 1974 (ERISA), which permits the Secretary of Labor to prescribe simplified annual reports for pension plans which cover fewer than 100 participants. Under section 104(a)(3), the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of section 104(a)(3), the Department of Labor has previously issued at 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46 and 2520.104b–10 certain simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans covering fewer than 100 participants and which satisfy certain other requirements.

Further, while some large employers may have small plans, in general most small plans are maintained by small employers. Thus, PWBA believes that assessing the impact of this proposed rule on small plans is an appropriate substitute for evaluating the effect on small entities. For purposes of their unified IFRA, the Departments adhered to PWBA's proposed definition of small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business which is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*). The Departments therefore request comments on the appropriateness of the size standard used in evaluating the impact of this proposed rule on small entities.

Under this proposed regulation, health plans generally may vary employee premium contributions or benefit levels across similarly situated individuals based on health factors only in connection with bona fide wellness programs. The regulation establishes four requirements for such bona fide wellness programs.

The Departments estimate that 36,000 plans with fewer than 100 participants vary employee premium contributions or benefit levels across similarly situated individuals based on health factors. While this represents just 1 percent of all small plans, the Departments nonetheless believe that it represents a substantial number of small entities. The Departments also note that at least some premium discounts or surcharges may be large. Premium discounts associated with wellness programs are believed to range as high as $560 per affected participant per year. Therefore, the Departments believe that the impact of this regulation on at least some small entities may be significant. Having reached these conclusions, the Departments carried out an IRFA as part of their unified analysis of the costs and benefits of the regulation. The reasoning and assumptions underlying the Departments' unified analysis of the regulation's costs and benefits are detailed later in this preamble.

The regulation's first requirement caps maximum allowable variation in employee premium contribution and benefit levels. The Departments estimate that 9,300 small plans will be affected by the cap. These plans can comply with this requirement by reducing premiums (or increasing benefits) by

$1.1 million on aggregate for those participants whose premiums are higher (or whose benefits are lower) due to health factors. This would constitute an ongoing, annual transfer of cost of $1.1 million, or $122 on average per affected plan. The regulation does not limit small plans' flexibility to transfer this cost back evenly to all participants in the form of small premium increases or benefit cuts.

The regulation's second requirement provides that wellness programs must be reasonably designed to promote health or prevent disease. Comments received by the Departments and available literature on employee wellness programs suggest that existing wellness programs generally satisfy this requirement. The requirement therefore is not expected to compel small plans to modify existing wellness programs. It is not expected to entail economic costs nor to prompt transfers.

The third requirement provides that rewards under wellness programs must be available to all similarly situated individuals. In particular, programs must allow individuals for whom it would be unreasonably difficult due to a medical condition to satisfy initial program standards an opportunity to satisfy reasonable alternative standards. The Departments believe that some small plans' wellness programs do not currently satisfy this requirement and will have to be modified.

The Departments estimate that 21,000 small plans' wellness programs include initial standards that may be unreasonably difficult for some participants to meet. These plans are estimated to include 18,000 participants for whom the standard is in fact unreasonably difficult to meet. (Many small plans are very small, having fewer than 10 participants, and many will include no participant for whom the initial standard is unreasonable difficult to meet for a medical reason.) Satisfaction of alternative standards by these participants will result in transfers of cost as they qualify for discounts or escape surcharges. If all of these participants request and then satisfy an alternative standard, the transfer would amount to $5 million annually. If one-half request alternative standards and one-half of those meet them, the transfer would amount to $1 million.

In addition to transfers, small plans will also incur new economic costs to provide alternative standards. However, plans can satisfy this requirement by providing inexpensive alternative standards, and have the flexibility to select whatever reasonable alternative standard is most desirable or cost efficient. Plans not wishing to provide alternative standards also have the option of abolishing health-status based variation in employee premiums. The Departments expect that the economic cost to provide alternatives combined with the associated transfer cost of granting discounts or waiving surcharges will not exceed the transfer cost associated with granting discounts or waiving surcharges for all participants who qualify for an alternative, estimated here at $1 million to $5 million, or about $55 to $221 per affected plan. Plans have the flexibility to transfer some or all of this cost evenly to all participants in the form of small premium increases or benefit cuts.

The fourth requirement provides that plan materials describing wellness plan standards must disclose the availability of reasonable alternative standards. This requirement will affect the 36,000 small plans that apply discounts or surcharges. These plans will incur economic costs to revise affected plan materials. The 5,000 to 18,000 small plan participants who will succeed at satisfying these alternative standards will benefit from these disclosures. The disclosures need not specify what alternatives are available, and the regulation provides model language that can be used to satisfy this requirement. Legal requirements other than this regulation generally require plans and issuers to maintain accurate materials describing plans. Plans and issuers generally update such materials on a regular basis as part of their normal business practices. This requirement is expected to represent a negligible fraction of the ongoing, normal cost of updating plans' materials. This analysis therefore attributes no cost to this requirement.

Special Analyses—Department of the Treasury

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that this notice of proposed rulemaking does not impose a collection of information on small entities and is not subject to section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5). For these reasons, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply pursuant to 5 U.S.C. section 603(a), which exempts from the Act's requirements certain rules involving the internal revenue laws. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Paperwork Reduction Act

Department of Labor and Department of the Treasury

This Notice of Proposed Rulemaking includes a requirement that if the plan materials describe the standard required to be met in order to qualify for a reward such as a premium discount or waiver of a cost-sharing requirement, they must also disclose the availability of a reasonable alternative standard. However, plan materials are not required to describe specific reasonable alternatives. The proposal also includes examples of disclosures which would satisfy the requirements of the proposed rule.

Plan administrators of group health plans covered under Title I of ERISA are required to make certain disclosures about the terms of a plan and material changes in terms through a Summary Plan Description or Summary of Material Modifications pursuant to sections 101(a) and 102(a) of ERISA. Group health plans and issuers also typically make other informational materials available to participants, either as a result of state and local requirements, or as part of their usual business practices in connection with the offer and promotion of health care coverage to employees.

While this proposal may cause group health plans to modify informational materials pertaining to wellness programs, the Departments conclude that it creates no new information collection requirements, and that the overall impact on existing information collection activities will be negligible. First, as described earlier, it is estimated that the proposed reasonable alternative requirements for bona fide wellness programs will impact a maximum of 22,000 plans and 229,000 participants. These numbers are very small in comparison with the 2.5 million ERISA group health plans that cover 65 million participants, and 175,500 state and local governmental plans that cover 11.5 million participants.

In addition, because model language is provided in the proposal, these modifications are expected to require a minimal amount of effort, such that they fall within the provision of OMB regulations in 5 CFR 1320.3(c)(2). This provision excludes from the definition of collection of information language which is supplied by the Federal government for disclosure purposes.

Finally, the Department of Labor's methodology in accounting for the burden of the Summary Plan

Description (SPD) and Summary of Material Modifications (SMM), as currently approved under OMB control number 1210–0039, incorporates an assumption concerning a constant rate of revision in these disclosure materials which is based on plans' actual reporting on the annual report/return (Form 5500) of their rates of modification. This occurrence of SPD revisions is generally more frequent than the minimum time frames described in section 104(b) and related regulations. The annual hour and cost burdens of the SMM/SPD information collection request is currently estimated at 576,000 hours and $97 million. Because the burden of modifying a wellness program's disclosures is expected to be negligible, and readily incorporated in other revisions made to plan materials on an ongoing basis, the methodology used already accounts for this type of change. Therefore, the Department concludes that the modification described in this proposal to the information collection request is neither substantive nor material, and accordingly it attributes no burden to this regulation.

Department of Health and Human Services

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(f) *Bona fide wellness programs* Paragraph (1)(iv) requires the plan or issuer to disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. However, in plan materials that merely mention that a program is available, without describing its terms, the disclosure is not required. This requirement will affect the estimated 1,300 nonfederal governmental plans that apply premium discounts or surcharges. The development of the materials is expected to take 100 hours for nonfederal governmental plans. The corresponding burden performed by service providers is estimated to be $38,000.

We have submitted a copy of this rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–2078–P,

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Allison Herron Eydt, HCFA–2078–P.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is subject to the provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and, if finalized, will be transmitted to Congress and the Comptroller General for review. The rule is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), as well as Executive Order 12875, this proposed rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor does it include mandates which may impose an annual burden of $100 million or more on the private sector.

Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these proposed regulations do not have federalism implications, because they do not have substantial direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. This is largely because, with respect to health insurance issuers, the vast majority of States have enacted laws which meet or exceed the federal standards in HIPAA prohibiting discrimination based on health factors. Therefore, the regulations are not likely to require substantial additional oversight of States by the Department of Health and Human Services.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) preserving the applicability of State laws establishing requirements for issuers of group health insurance coverage, except to the extent that these requirements prevent the application of the portability, access, and renewability requirements of HIPAA. The nondiscrimination provisions that are the subject of this rulemaking are included among those requirements.

In enacting these new preemption provisions, Congress indicated its intent to establish a preemption of State insurance requirements only to the extent that those requirements prevent the application of the basic protections set forth in HIPAA. HIPAA's Conference Report states that the conferees intended the narrowest preemption of State laws with regard to health insurance issuers. H.R. Conf. Rep. No. 736, 104th Cong. 2d Session 205 (1996). Consequently, under the statute and the Conference Report, State insurance laws that are more stringent than the federal requirements are unlikely to ''prevent the application of'' the HIPAA nondiscrimination provisions.

Accordingly, States are given significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law. In many cases, the federal law imposes minimum requirements which States are free to exceed. Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 and these regulations do not reduce the discretion given to the States by the statute. It is the Departments' understanding that the vast majority of States have in fact implemented provisions which meet or exceed the minimum requirements of the HIPAA non-discrimination provisions.

HIPAA provides that the States may enforce the provisions of HIPAA as they pertain to issuers, but that the Secretary of Health and Human Services must enforce any provisions that a State fails to substantially enforce. When exercising its responsibility to enforce the provisions of HIPAA, HCFA works cooperatively with the States for the purpose of addressing State concerns and avoiding conflicts with the exercise of State authority.[2] HCFA has developed procedures to implement its enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA's requirements in the first instance. HCFA's procedures address the handling of reports that States may not be enforcing HIPAA's requirements, and the mechanism for allocating enforcement responsibility between the States and HCFA. To date, HCFA has had occasion to enforce the HIPAA non-discrimination provisions in only two States.

Although the Departments conclude that these proposed regulations do not have federalism implications, in keeping with the spirit of the Executive Order that agencies closely examine any policies that may have federalism implications or limit the policy making discretion of the States, the Department of Labor and HCFA have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials.

For example, the Departments were aware that some States commented on the way the federal provisions should be interpreted. Therefore, the Departments have sought and received input from State insurance regulators and the National Association of Insurance Commissioners (NAIC). The NAIC is a non-profit corporation established by the insurance commissioners of the 50 States, the District of Columbia, and the four U.S. territories, that among other things provides a forum for the development of uniform policy when uniformity is appropriate. Its members meet, discuss, and offer solutions to mutual problems. The NAIC sponsors quarterly meetings to provide a forum for the exchange of ideas, and in-depth consideration of insurance issues by regulators, industry representatives, and consumers. HCFA and Department of Labor staff have attended the quarterly meetings consistently to listen to the concerns of the State Insurance Departments regarding HIPAA issues, including the nondiscrimination provisions. In addition to the general discussions, committee meetings and task groups, the NAIC sponsors the following two standing HIPAA meetings for members during the quarterly conferences:

- HCFA/DOL Meeting on HIPAA Issues (This meeting provides HCFA and Labor the opportunity to provide updates on regulations, bulletins, enforcement actions and outreach efforts regarding HIPAA.)
- The NAIC/HCFA Liaison Meeting (This meeting provides HCFA and the NAIC the opportunity to discuss HIPAA and other health care programs.)

In their comments on the 1997 interim rules, the NAIC suggested that the permissible standards for determining bona fide wellness programs ensure that such programs are not used as a proxy for discrimination based on a health factor. The NAIC also commented that the nondiscrimination provisions of HIPAA ''are especially significant in their impact on small groups, and particularly in small groups, where there is a great potential for adverse selection and gaming.'' One State asked that the Departments' final nondiscrimination provisions be as consumer-protective as possible. Finally, another State described already-existing State regulation of issuers offering wellness programs in that State and asked that standards for bona fide wellness programs be left to the States.

The Departments considered these views very carefully when formulating the wellness program proposal. While allowing plans a great deal of flexibility in determining what kinds of incentives best encourage the plan's own participants and beneficiaries to pursue a healthier lifestyle, the Departments proposal ensures that individuals have an opportunity to qualify for the premium discount or other reward. If an individual is unable to satisfy a wellness program standard due to a health factor, plans are required to make a reasonable alternative standard available to the individual. In addition, the Departments reiterate their position that State insurance laws that are more stringent than the federal requirements are unlikely to ''prevent the application of'' the federal law and therefore are saved from preemption. Therefore, these more protective State laws continue to apply for individuals receiving health insurance coverage in connection with a group health plan.

The Departments welcome further comment on these issues from the States in response to this proposal.

The Departments also cooperate with the States in several ongoing outreach initiatives, through which information on HIPAA is shared among federal regulators, State regulators, and the regulated community. In particular, the Department of Labor has established a Health Benefits Education Campaign with more than 70 partners, including HCFA, NAIC and many business and consumer groups. HCFA has sponsored four conferences with the States—the Consumer Outreach and Advocacy conferences in March 1999 and June 2000, the Implementation and Enforcement of HIPAA National State-Federal Conferences in August 1999 and 2000. Furthermore, both the Department of Labor and HCFA websites offer links to important State websites and other resources, facilitating coordination between the State and federal regulators and the regulated community.

In conclusion, throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA, the

[2] This authority applies to insurance issued with respect to group health plans generally, including plans covering employees of church organizations. Thus, this discussion of federalism applies to all group health insurance coverage that is subject to the PHS Act, including those church plans that provide coverage through a health insurance issuer (but not to church plans that do not provide coverage through a health insurance issuer). For additional information relating to the application of these nondiscrimination rules to church plans, see the preamble to regulations being proposed elsewhere in this issue of the **Federal Register** regarding section 9802(c) of the Code relating to church plans.

Departments have attempted to balance the States' interests in regulating health plans and health insurance issuers, and the rights of those individuals that Congress intended to protect through the enactment of HIPAA.

Unified Analysis of Costs and Benefits—Department of Labor and Department of Health and Human Services

Introduction

Under the proposed regulation, health plans generally may vary employee premium contributions or benefit levels across similarly situated individuals based on health factors only in connection with bona fide wellness programs. The regulation establishes four requirements for such bona fide wellness programs.

A large body of literature, together with comments received by the Departments, demonstrate that well-designed wellness programs can deliver benefits well in excess of their costs. For example, the U.S. Centers for Disease Control and Prevention estimate that implementing proven clinical smoking cessation interventions can save one year of life for each $2,587 invested. In addition to reduced mortality, benefits of effective wellness programs can include reduced absenteeism, improved productivity, and reduced medical costs. The requirements contained in the proposed regulation were crafted to accommodate and not impair such beneficial programs, while combating discrimination in eligibility and premiums for similarly situated individuals as intended by Congress.

Detailed Estimates

Estimation of the economic impacts of the four requirements is difficult because data on affected plans' current practices are incomplete, and because plans' approaches to compliance with the requirements and the effects of those approaches will vary and cannot be predicted. Nonetheless, the Departments undertook to consider the impacts fully and to develop estimates based on reasonable assumptions.

Based on a 1993 survey of employers by the Robert Wood Johnson Foundation, the Departments estimate that 1.6 percent of large plans and 1.2 percent of small plans currently vary employee premium contributions across similarly situated individuals and will be subject to the four requirements for bona fide wellness programs. This amounts to 32,000 plans covering 1.2 million participants. According to an industry survey by Hewitt Associates, just more than one-third as many plans vary benefit levels across similarly situated individuals as vary premiums. This amounts to 11,000 plans covering 415,000 participants. The Departments separately considered the effect of each of the four requirements on these plans. For purposes of its estimates, the Departments assumed that one-half of the plans in the latter group are also included in the former, thereby estimating that 37,000 plans covering 1.4 million participants will be subject to the four requirements for bona fide wellness programs.

Limit on Dollar Amount—Under the first requirement, any discount or surcharge, whether applicable to employee premiums or benefit levels, must not exceed a specified percentage of the total premium for employee-only coverage under the plan. The proposed regulations specify three alternative percentages: 10, 15, and 20. For purposes of this discussion, the Departments examine the midpoint of the three alternative percentages, 15 percent.

The Departments lack representative data on the magnitude of the discounts and surcharges applied by affected plans today. One leading consultant practicing in this area believes that wellness incentive premium discounts ranged from about $60 to about $480 annually in 1998, averaging about $240 that year. Expressed as a percentage of average total premium for employee-only coverage that year, this amounts to a range of about 3 percent to 23 percent and an average of about 11 percent. This suggests that most affected plans, including some whose discounts are somewhat larger than average, already comply with the first requirement and will not need to reduce the size of the discounts or surcharges they apply. It appears likely, however, that a sizeable minority of plans—perhaps a few thousand plans covering a few hundred thousand participants—will need to reduce the size of their discounts or surcharges in order to comply with the first requirement. The table below summarizes the Departments' assumptions regarding the size of discounts and surcharges at year 2000 levels, expressed in annual amounts.

The Departments considered the potential economic effects of requiring these plans to reduce the size of their discounts or surcharges. These effects are likely to include transfers of costs among plan sponsors and participants, as well as new economic costs and benefits.

	Percent	Dollars
Single employee total premium	.....	$2,448
Discount or Surcharge:		
low	3	70
average	11	280
high	23	560
Cap on discount or surcharge	15	367

Transfers will arise as plans reduce discounts and surcharges. Plan sponsors can exercise substantial control over the size and direction of these transfers. Limiting the size of discounts and surcharges restricts only the differential treatment of participants who satisfy wellness program standards and those who do not. It does not, for example, restrict plans sponsors' flexibility to determine the respective employer and employee shares of base premiums. Possible outcomes include a transfer of costs to plan sponsors from participants who satisfy wellness program standards, from plan sponsors to participants who do not satisfy the standards, from participants who satisfy the standards to those who do not, or some combination of these.

The Departments developed a very rough estimate of the total amount of transfers that might derive from this requirement. The Departments' estimate assumes that (1) all discounts and surcharges take the form of employee premium discounts; (2) discounts are distributed evenly within both the low-to-average range and the average-to-high range, and are distributed across these ranges such that their mean equals the assumed average; and (3) 70 percent of participants qualify for the discount. This implies that just more than one-fourth of plans with discounts or surcharges will be impacted by the cap, and that these plans' current discounts and surcharges exceed the cap by $86 on average. The 9,600 affected plans could satisfy this requirement by reducing premiums for the 106,000 participants who do not qualify by $86 annually, for an aggregate, ongoing annual transfer of approximately $9 million. The Departments solicit comments on their assumptions and estimate, and would welcome information supportive of better estimates.

New economic costs and benefits may arise if changes in the size of discounts or surcharges result in changes in participant behavior.

Net economic welfare might be lost if some wellness programs' effectiveness is eroded, but the magnitude and incidence of such effects is expected to be negligible. Consider a wellness program that discounts premiums for

participants who take part in an exercise program. It is plausible that, at the margin, a few participants who would take part in order to obtain a discount of between $368 and $560 annually will not take part to obtain a discount of $367. This might represent a net loss of economic welfare. This effect is expected to be negligible, however. Based on the assumptions specified above, just 248,000 participants now qualifying for discounts would be affected. Reductions in discounts are likely to average about $86 annually, which amounts to $7 per month or $3 per biweekly pay period. Employee premiums are often deducted from pay pre-tax, so the after tax value of these discounts may be even smaller. Moreover, the proposed regulation caps only discounts and surcharges applied to similarly situated individuals in the context of a group health plans. It does not restrict plan sponsors from employing other motivational tools to encourage participation in wellness programs. According to the Hewitt survey, among 408 employers that offered incentives for participation in wellness programs, 24 percent offered awards or gifts and 62 percent varied life insurance premiums, while just 14 percent varied medical premiums.

On the other hand, net economic welfare likely will be gained in instances where large premium differentials would otherwise have served to discourage enrollment in health plans by employees who did not satisfy wellness program requirements. Consider a plan that provides a very large discount for non-smokers. The very high employee premiums charged to smokers might discourage some from enrolling in the plan at all, and some of these might be uninsured as a result. It seems unlikely that the plan sponsor would respond to the first requirement of the proposed regulation by raising premiums drastically for all non-smokers, driving many out of the plan. Instead, the plan sponsor would reduce premiums for smokers, and more smokers would enroll. This would result in transfers to newly enrolled smokers from the plan sponsor (and possibly from non-smokers if the plan sponsor makes other changes to compensation). But it would also result in net gains in economic welfare from reduced uninsurance.

The Departments believe that the net economic gains from prohibiting discounts and surcharges so large that they could discourage enrollment based on health factors outweigh any net losses that might derive from the negligible reduction of some employees' incentive to participate in wellness programs. Comments are solicited on the magnitude of these and any other effects and on the attendant costs and benefits.

Reasonable Design—Under the second requirement, the program must be reasonably designed to promote health or prevent disease. The Departments believe that a program that is not so designed would not provide economic benefits, but would serve merely to transfer costs from plan sponsors to targeted individuals based on health factors. This requirement therefore is not expected to impose economic costs but might prompt transfers of costs from otherwise targeted individuals to their plans' sponsors (or to other participants in their plans if plan sponsors elect to pass these costs back evenly to all participants). Comments received by the Departments and available literature on employee wellness programs, however, suggest that existing wellness programs generally satisfy this requirement. The requirement therefore is not expected to compel plans to modify existing wellness programs. It is not expected to entail economic costs nor to prompt transfers. The Departments would appreciate comments on this conclusion and information on the types of existing wellness programs (if any) that would not satisfy requirement.

Uniform Availability—The third requirement provides that rewards under the program must be available to all similarly situated individuals. In particular, the program must allow any individual for whom it would be unreasonably difficult due to a medical condition to satisfy the initial program standard an opportunity to satisfy a reasonable alternative standard. Comments received by the Departments and available literature on employee wellness programs suggest that some wellness programs do not currently satisfy this requirement and will have to be modified. Based on the Hewitt survey, the Departments estimate that among employers that provide incentives for employees to participate in wellness programs, 18 percent require employees to achieve a low risk behavior to qualify for the incentive, 79 percent require a pledge of compliance, and 38 percent require participation in a program. (These numbers sum to more than 100 percent because wellness programs may apply more than one criterion.) Depending on the nature of the wellness program, it might be unreasonably difficult due to a medical condition for at least some plan participants to achieve the behavior or to comply with or participate in the program.

The Departments identified three broad types of economic impact that might arise from the third requirement. First, affected plans will incur some economic cost to make available reasonable alternative standards. Second, additional economic costs and benefits may arise depending on the nature of alternatives provided, individuals' use of these alternatives, and any changes in the affected individuals' behavioral and health outcomes. Third, some costs may be transferred from individuals who would fail to satisfy programs' initial standards, but who will satisfy reasonable alternative standards once available (and thereby qualify for associated discounts), to plan sponsors (or to other participants in their plans if plan sponsors elect to pass these costs back evenly to all participants).

The Departments note that some plans that apply different discounts or surcharges to similarly situated individuals and are therefore subject to the requirement may not need to provide alternative standards. The requirement provides that alternative standards need not be specified or provided until a participant for whom it is unreasonably difficult due to a medical condition to satisfy the initial standard seeks such an alternative. Some wellness programs' initial standards may be such that no participant would ever find them unreasonably difficult to satisfy due to a medical condition. The Departments reviewed Hewitt survey data on wellness program standards and criteria. Based on their review they estimate that 20,000 of the 35,000 potentially affected plans have initial wellness program standards that might be unreasonably difficult for some participants to satisfy due to a medical condition. Moreover, because alternatives need not be made available until they are sought by qualified plan participants, it might be possible for some of these plans to go for years or even indefinitely without needing to make available an alternative standard. This could be particularly likely for small plans. The most common standards for wellness programs pertain to smoking, blood pressure, and cholesterol levels, according to the Hewitt Survey. Based on U.S. Centers for Disease Control and Management data on the incidence of certain health habits and conditions in the general population, the Departments estimate that among companies with 5 employees, about one-fourth probably employ no smokers, and about one-third probably employ no one with high blood pressure or cholesterol.

Approximately 96 percent of all plans with potentially difficult initial wellness program standards have fewer than 100 participants.

How many participants might qualify for, seek, and ultimately satisfy alternative standards? The Departments lack sufficient data to estimate these counts with confidence. Rough estimates were developed as follows. The Departments examined the Hewitt survey of wellness program provisions and U.S. Centers for Disease Control and Prevention statistics on the incidence of certain health habits and conditions in the general population in order to discern how wellness programs' initial standards might interact with plan participants' health habits and health status. Based on these data, it appears that as many as 29 percent of participants in plans with discounts or surcharges, or 394,000 individuals, might fail to satisfy wellness programs' initial standards. Of these, approximately 229,000 are in the 22,000 plans which apply standards that might be unreasonably difficult due to a medical condition for some plan participants to satisfy, the Departments estimate. The standards would in fact be unreasonably difficult to satisfy for some subset of these individuals—148,000 by the Departments' estimate. The Departments lack any basis to estimate how many of these will avail themselves of an alternative standard, or how many that do will succeed in satisfying that standard. To estimate the potential impact of this requirement, the Departments considered two assumptions: an upper bound assumption under which all 148,000 individuals seek and satisfy alternative standards, and an alternative assumption under which one-half (or 74,000) seek an alternative and one-half of those (37,000) satisfy it.

Where plans are required to make available reasonable alternative standards, what direct costs will they incur? The regulation does not prescribe a particular type of alternative standard that must be provided. Instead, it permits plan sponsors flexibility to provide any reasonable alternative. The Departments expect that plans sponsors will select alternatives that entail the minimum net costs (or, stated differently, the maximum net benefits) that are possible. Plan sponsors may select low-cost alternatives, such as requiring an individual for whom it would be unreasonably difficult to quit smoking (and thereby qualify for a non-smoker discount) to attend a smoking cessation program that is available at little or no cost in the community, or to watch educational videos or review educational literature. Plan sponsors presumably will select higher-cost alternatives only if they thereby derive offsetting benefits, such as a higher smoking cessation success rate. The Departments also note that the number of plans with initial wellness program standards that might be unreasonably difficult for some participants to satisfy is probably small (having been estimated at 22,000, or 1 percent of all plans), as is the number of individuals who would take advantage of alternative standards (estimated at between 74,000 and 148,00, or between 0.1 percent and 0.2 percent of all participants).

It seems reasonable to presume that the net cost plan sponsors will incur in the provision of alternatives, including transfers as well as new economic costs and benefits, will not exceed the transfer cost of providing discounts (or waiving surcharges) for all plan participants who qualify for alternatives, which is estimated below at between $9 million and $37 million. It is likely that many plan sponsors will find more cost effective ways to satisfy this requirement, and that the true net cost to them will therefore be much smaller than this. The Departments have no basis for estimating the magnitude of the cost of providing alternative standards or of potential offsetting benefits, however, and therefore solicit comments from the public on this question.

What other economic costs and benefits might arise where alternative standards are made available? A large number of outcomes are possible. Consider a program that provides premium discounts for non-smokers.

It is possible that some individuals who would have quit smoking in order to qualify for a discount will nonetheless find it unreasonably difficult to quit and will obtain the discount while continuing to smoke by satisfying an alternative standard. This would represent a net loss of economic welfare from increased smoking.

On the other hand, consider individuals who, in the context of the initial program, are unable or unwilling to quit smoking. It seems likely that some of these individuals could quit with appropriate assistance, and that some alternative standards provided by plan sponsors will provide such assistance. In such cases, a program which had the effect of shifting premium costs to smokers would be transformed into one that successfully reduced smoking. This would represent a net gain of economic welfare.

Which scenario is more likely? The Departments have no concrete basis for answering this question, and therefore solicit comments on it. However, the Departments note that plan sponsors will have strong motivation to identify and provide alternative standards that have positive net economic effects. They will be disinclined to provide alternatives that undermine their overall wellness program and worsen behavioral and health outcomes, or that make financial rewards available absent meaningful efforts by participants to improve their health habits and health. Instead they will be inclined to provide alternatives that sustain or reinforce plan participants' incentive to improve their health habits and health, and/or that help participants make such improvements. It therefore seems likely that gains in economic welfare from this requirement will equal or outweigh losses. The Departments anticipate that the requirement to provide reasonable alternative standards will reduce instances where wellness programs serve only to shift costs to higher risk individuals and increase instances where programs succeed at helping high risk individuals improve their health habits and health.

What transfers of costs might derive from the availability of (and participants' satisfaction of) alternative standards? The transfers arising from this requirement may take the form of transfers to participants who satisfy new alternative wellness program standards from plan sponsors, to such participants from other participants, or some combination of these. The Departments estimated potential transfers as follows. Assuming average annual total premiums for employee-only coverage of $2,448,[3] the maximum allowable discount of 15 percent amounts to $367 per year. As noted earlier, discounts under existing wellness programs appear to average about 11 percent (or $280 per year for a plan costing $2,448), ranging from 3 percent ($70) to 23 percent ($560). Reducing all discounts greater than $367 per year to that amount will reduce the average, perhaps to about $251. Assuming that the 37,000 to 148,000 participants who satisfy alternative standards would not have satisfied the wellness programs' initial standards, the transfers attributable to their discounts and hence to this requirement would amount to between $9 million and $37 million. The Departments solicit comments on their assumptions and estimates regarding

[3] Average level based on the Kaiser Family Foundation/Health Research and Education Trust Survey of Employer-Sponsored Health benefits, 1999, projected by the Departments to 2000 levels.

transfers that may derive from this requirement.

Disclosure of Alternatives' Availability—The fourth requirement provides that plan materials describing wellness plan standards must disclose the availability of reasonable alternative standards. This requirement will affect the 37,000 plans that apply discounts or surcharges. These plans will incur economic costs to revise affected plan materials. The 37,000 to 148,000 participants who will succeed at satisfying these alternative standards will benefit from these disclosures. The disclosures need not specify what alternatives are available, and the regulation provides model language that can be used to satisfy this requirement. The Departments generally account elsewhere for plans' cost of updating such materials to reflect changes in plan provisions as required under various disclosure requirements and as is part of usual business practice. This particular requirement is expected to represent a negligible fraction of the ongoing cost of updating plans' materials, and is not separately accounted for here.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Employee benefit plans, Employee Retirement Income Security Act, Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 54.9802–1 is amended by adding text to paragraph (b) to read as follows:

§ 54.9802–1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) *Bona fide wellness programs*—(1) *Definition.* A wellness program is a bona fide wellness program if it satisfies the requirements of paragraphs (f)(1)(i) through (f)(1)(iv) of this section. However, a wellness program providing a reward that is not contingent on satisfying a standard related to a health factor does not violate this section even if it does not satisfy the requirements of this paragraph (f) for a bona fide wellness program.

(i) The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed (10/15/20) percent of the cost of employee-only coverage under the plan. For this purpose, the cost of employee-only coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is receiving coverage. A reward can be in the form of a discount, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge.

(ii) The program must be reasonably designed to promote good health or prevent disease. For this purpose, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(iii) The reward under the program must be available to all similarly situated individuals. A reward is not available to all similarly situated individuals for a period unless the program allows—

(A) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard for the reward; and

(B) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard for the reward.

(iv) The plan must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. (However, in plan materials that merely mention that a program is available, without describing its terms, this disclosure is not required.) The following language, or substantially similar language, can be used to satisfy this requirement: ''If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward.'' In addition, other examples of language that would satisfy this requirement are set forth in Examples 4, 5, and 6 of paragraph (f)(2) of this section.

(2) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan offers a wellness program to participants and beneficiaries under which the plan provides memberships to a local fitness center at a discount.

(ii) *Conclusion.* In this *Example 1,* the reward under the program is not contingent on satisfying any standard that is related to a health factor. Therefore, there is no discrimination based on a health factor under either paragraph (b) or (c) of this section and the requirements for a bona fide wellness program do not apply.

Example 2. (i) *Facts.* An employer sponsors a group health plan. The annual premium for employee-only coverage is $2,400 (of which the employer pays $1,800 per year and the employee pays $600 per year). The plan implements a wellness program that offers a $240 rebate on premiums to program enrollees.

(ii) *Conclusion.* In this Example 2, the program satisfies the requirements of paragraph (f)(1)(i) of this section because the reward for the wellness program, $240, does not exceed [10/15/20] percent of the total annual cost of employee-only coverage, [$240/$360/$480]. ($2,400 x [10/15/20]% = [$240/$360/$480].)

Example 3. (i) *Facts.* A group health plan gives an annual premium discount of [10/15/20] percent of the cost of employee-only coverage to participants who adhere to a wellness program. The wellness program consists solely of giving an annual cholesterol test to participants. Those participants who achieve a count under 200 receive the premium discount for the year.

(ii) *Conclusion.* In this *Example 3,* the program is not a bona fide wellness program. The program fails to satisfy the requirement of being available to all similarly situated individuals because some participants may be unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard for obtaining the premium discount. (In addition, plan materials describing the program are required to disclose the availability of the reasonable alternative standard for obtaining the premium discount.) Thus, the premium discount violates paragraph (c) of this section because it may require an individual to pay a higher premium based on a health factor of the individual than is required of a similarly situated individual under the plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except that if it is unreasonably

difficult due to a medical condition for a participant to achieve the targeted cholesterol count (or if it is medically inadvisable for a participant to attempt to achieve the targeted cholesterol count), the plan will make available a reasonable alternative standard that takes the relevant medical condition into account. In addition, all plan materials describing the terms of the program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.'' Individual *D* is unable to achieve a cholesterol count under 200. The plan accommodates *D* by making the discount available to *D*, but only if *D* complies with a low-cholesterol diet.

(ii) *Conclusion.* In this *Example 5,* the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve the targeted count (or for whom it is medically inadvisable to attempt to achieve the targeted count) in the prescribed period by providing a reasonable alternative standard. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium discount does not violate this section.

Example 5. (i) *Facts.* A group health plan will waive the $250 annual deductible (which is less than [10/15/20] percent of the annual cost of employee-only coverage under the plan) for the following year for participants who have a body mass index between 19 and 26, determined shortly before the beginning of the year. However, any participant for whom it is unreasonably difficult due to a medical condition to attain this standard (and any participant for whom it is medically inadvisable to attempt to achieve this standard) during the plan year is given the same discount if the participant walks for 20 minutes three days a week. Any participant for whom it is unreasonably difficult due to a medical condition to attain either standard (and any participant for whom it is medically inadvisable to attempt to achieve either standard during the year) is given the same discount if the individual satisfies a reasonable alternative standard that is tailored to the individual's situation. All plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a body mass index between 19 and 26 (or if it is medically inadvisable for you to attempt to achieve this body mass index) this year, your deductible will be waived if you walk for 20 minutes three days a week. If you cannot follow the walking program, call us at the number above and we will work with you to develop another way to have your deductible waived, such as a dietary regimen.''

(ii) *Conclusion.* In this *Example 5,* the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it generally accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve (or for whom it is medically inadvisable to attempt to achieve) the targeted body mass index by providing a reasonable alternative standard (walking) and it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to walk by providing an alternative standard that is reasonable for the individual. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard for every individual. Thus, the waiver of the deductible does not violate this section.

Example 6. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a form for participants to certify that they have not used tobacco products in the preceding twelve months. Participants who do not provide the certification are assessed a surcharge that is [10/15/20] percent of the cost of employee-only coverage. However, all plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to meet the requirements under this program (or if it is medically inadvisable for you to attempt to meet the requirements of this program), we will make available a reasonable alternative standard for you to avoid this surcharge.'' It is unreasonably difficult for Individual *E* to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates *E* by requiring *E* to participate in a smoking cessation program to avoid the surcharge. *E* can avoid the surcharge for as long as *E* participates in the program, regardless of whether *E* stops smoking (as long as *E* continues to be addicted to nicotine).

(ii) *Conclusion.* In this *Example 6,* the premium surcharge is permissible as a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to quit using tobacco products by providing a reasonable alternative standard. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium surcharge does not violate this section.

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

For the reasons set forth above, 29 CFR Part 2590 is proposed to be amended as follows:

PART 2590 [AMENDED]—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority: Secs. 107, 209, 505, 701–703, 711–713, and 731–734 of ERISA (29 U.S.C. 1027, 1059, 1135, 1171–1173, 1181–1183, and 1191–1194), as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436), section 101(g)(4) of HIPAA, and Secretary of Labor's Order No. 1–87, 52 FR 13139, April 21, 1987.

2. Section 2590.702 is proposed to be amended by adding text to paragraph (b) to read as follows:

§ 2590.702 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) *Bona fide wellness programs*—(1) *Definition.* A wellness program is a bona fide wellness program if it satisfies the requirements of paragraphs (f)(1)(i) through (f)(1)(iv) of this section. However, a wellness program providing a reward that is not contingent on satisfying a standard related to a health factor does not violate this section even if it does not satisfy the requirements of this paragraph (f) for a bona fide wellness program.

(i) The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed [10/15/20] percent of the cost of employee-only coverage under the plan. For this purpose, the cost of employee-only coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is receiving coverage. A reward can be in the form of a discount, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge.

(ii) The program must be reasonably designed to promote good health or

prevent disease. For this purpose, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(iii) The reward under the program must be available to all similarly situated individuals. A reward is not available to all similarly situated individuals for a period unless the program allows—

(A) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard for the reward; and

(B) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard for the reward.

(iv) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. (However, in plan materials that merely mention that a program is available, without describing its terms, this disclosure is not required.) The following language, or substantially similar language, can be used to satisfy this requirement: ''If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward.'' In addition, other examples of language that would satisfy this requirement are set forth in Examples 4, 5, and 6 of paragraph (f)(2) of this section.

(2) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a wellness program to participants and beneficiaries under which the plan provides memberships to a local fitness center at a discount.

(ii) *Conclusion.* In this *Example 1,* the reward under the program is not contingent on satisfying any standard that is related to a health factor. Therefore, there is no discrimination based on a health factor under either paragraph (b) or (c) of this section and the requirements for a bona fide wellness program do not apply.

Example 2. (i) *Facts.* An employer sponsors a group health plan. The annual premium for employee-only coverage is $2,400 (of which the employer pays $1,800 per year and the employee pays $600 per year). The plan implements a wellness program that offers a $240 rebate on premiums to program enrollees.

(ii) *Conclusion.* In this *Example 2,* the program satisfies the requirements of paragraph (f)(1)(i) of this section because the reward for the wellness program, $240, does not exceed [10/15/20] percent of the total annual cost of employee-only coverage, [$240/$360/$480]. ($2,400 x [10/15/20]% = [$240/$360/$480].)

Example 3. (i) *Facts.* A group health plan gives an annual premium discount of [10/15/20] percent of the cost of employee-only coverage to participants who adhere to a wellness program. The wellness program consists solely of giving an annual cholesterol test to participants. Those participants who achieve a count under 200 receive the premium discount for the year.

(ii) *Conclusion.* In this *Example 3,* the program is not a bona fide wellness program. The program fails to satisfy the requirement of being available to all similarly situated individuals because some participants may be unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard for obtaining the premium discount. (In addition, plan materials describing the program are required to disclose the availability of the reasonable alternative standard for obtaining the premium discount.) Thus, the premium discount violates paragraph (c) of this section because it may require an individual to pay a higher premium based on a health factor of the individual than is required of a similarly situated individual under the plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except that if it is unreasonably difficult due to a medical condition for a participant to achieve the targeted cholesterol count (or if it is medically inadvisable for a participant to attempt to achieve the targeted cholesterol count), the plan will make available a reasonable alternative standard that takes the relevant medical condition into account. In addition, all plan materials describing the terms of the program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.'' Individual *D* is unable to achieve a cholesterol count under 200. The plan accommodates *D* by making the discount available to *D,* but only if *D* complies with a low-cholesterol diet.

(ii) *Conclusion.* In this *Example 4,* the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve the targeted count (or for whom it is medically inadvisable to attempt to achieve the targeted count) in the prescribed period by providing a reasonable alternative standard. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium discount does not violate this section.

Example 5. (i) *Facts.* A group health plan will waive the $250 annual deductible (which is less than [10/15/20] percent of the annual cost of employee-only coverage under the plan) for the following year for participants who have a body mass index between 19 and 26, determined shortly before the beginning of the year. However, any participant for whom it is unreasonably difficult due to a medical condition to attain this standard (and any participant for whom it is medically inadvisable to attempt to achieve this standard) during the plan year is given the same discount if the participant walks for 20 minutes three days a week. Any participant for whom it is unreasonably difficult due to a medical condition to attain either standard (and any participant for whom it is medically inadvisable to attempt to achieve either standard during the year) is given the same discount if the individual satisfies a reasonable alternative standard that is tailored to the individual's situation. All plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a body mass index between 19 and 26 (or if it is medically inadvisable for you to attempt to achieve this body mass index) this year, your deductible will be waived if you walk for 20 minutes three days a week. If you cannot follow the walking program, call us at the number above and we will work with you to develop another way to have your deductible waived, such as a dietary regimen.''

(ii) *Conclusion.* In this *Example 5,* the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it generally accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve (or for whom it is medically inadvisable to attempt to achieve) the targeted body mass index by providing a reasonable alternative standard (walking) and it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to walk by providing an alternative standard that is reasonable for the individual. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard for every individual. Thus, the waiver of the deductible does not violate this section.

Example 6. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a form for participants to certify that they have not used tobacco products in the preceding twelve months.

Participants who do not provide the certification are assessed a surcharge that is [10/15/20] percent of the cost of employee-only coverage. However, all plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a health factor for you to meet the requirements under this program (or if it is medically inadvisable for you to attempt to meet the requirements of this program), we will make available a reasonable alternative standard for you to avoid this surcharge.'' It is unreasonably difficult for Individual *E* to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates *E* by requiring *E* to participate in a smoking cessation program to avoid the surcharge. *E* can avoid the surcharge for as long as *E* participates in the program, regardless of whether *E* stops smoking (as long as *E* continues to be addicted to nicotine).

(ii) *Conclusion.* In this *Example 6,* the premium surcharge is permissible as a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to quit using tobacco products by providing a reasonable alternative standard. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium surcharge does not violate this section.

* * * * *

Signed at Washington, DC this 28th day of December, 2000.

Leslie B. Kramerich,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

For the reasons set forth above, we propose to amend 45 CFR Part 146 as follows:

PART 146 [AMENDED]—RULES AND REGULATIONS FOR HEALTH INSURANCE PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 146 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791 and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92 as amended by HIPAA (Public Law 104–191, 110 Stat. 1936), MHPA and NMHPA (Public Law 104–204, 110 Stat. 2935), and WHCRA (Public Law 105–277, 112 Stat. 2681–436), and section 102(c)(4) of HIPAA.

2. We propose to amend § 146.121 by adding text to paragraph (b) to read as follows:

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) *Bona fide wellness programs*—(1) *Definition.* A wellness program is a bona fide wellness program if it satisfies the requirements of paragraphs (f)(1)(i) through (f)(1)(iv) of this section. However, a wellness program providing a reward that is not contingent on satisfying a standard related to a health factor does not violate this section even if it does not satisfy the requirements of this paragraph (f) for a bona fide wellness program.

(i) The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed [10/15/20] percent of the cost of employee-only coverage under the plan. For this purpose, the cost of employee-only coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is receiving coverage. A reward can be in the form of a discount, a rebate of a premium or contribution, or a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), or the absence of a surcharge.

(ii) The program must be reasonably designed to promote good health or prevent disease. For this purpose, a program is not reasonably designed to promote good health or prevent disease unless the program gives individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(iii) The reward under the program must be available to all similarly situated individuals. A reward is not available to all similarly situated individuals for a period unless the program allows—

(A) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard for the reward; and

(B) A reasonable alternative standard to obtain the reward to any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard for the reward.

(iv) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard required under paragraph (f)(1)(iii) of this section. (However, in plan materials that merely mention that a program is available, without describing its terms, this disclosure is not required.) The following language, or substantially similar language, can be used to satisfy this requirement: ''If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward.'' In addition, other examples of language that would satisfy this requirement are set forth in Examples 4, 5, and 6 of paragraph (f)(2) of this section.

(2) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a wellness program to participants and beneficiaries under which the plan provides memberships to a local fitness center at a discount.

(ii) Conclusion. In this *Example 1,* the reward under the program is not contingent on satisfying any standard that is related to a health factor. Therefore, there is no discrimination based on a health factor under either paragraph (b) or (c) of this section and the requirements for a bona fide wellness program do not apply.

Example 2. (i) *Facts.* An employer sponsors a group health plan. The annual premium for employee-only coverage is $2,400 (of which the employer pays $1,800 per year and the employee pays $600 per year). The plan implements a wellness program that offers a $240 rebate on premiums to program enrollees.

(ii) *Conclusion.* In this *Example 2,* the program satisfies the requirements of paragraph (f)(1)(i) of this section because the reward for the wellness program, $240, does not exceed [10/15/20] percent of the total annual cost of employee-only coverage, [$240/$360/$480]. ($2,400 x [10/15/20]% = [$240/$360/$480].)

Example 3. (i) *Facts.* A group health plan gives an annual premium discount of [10/15/20] percent of the cost of employee-only coverage to participants who adhere to a wellness program. The wellness program consists solely of giving an annual cholesterol test to participants. Those participants who achieve a count under 200 receive the premium discount for the year.

(ii) *Conclusion.* In this *Example 3,* the program is not a bona fide wellness program. The program fails to satisfy the requirement of being available to all similarly situated individuals because some participants may be unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard for obtaining the premium discount. (In addition, plan materials describing the program are required to disclose the availability of the reasonable alternative standard for obtaining the premium

discount.) Thus, the premium discount violates paragraph (c) of this section because it may require an individual to pay a higher premium based on a health factor of the individual than is required of a similarly situated individual under the plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except that if it is unreasonably difficult due to a medical condition for a participant to achieve the targeted cholesterol count (or if it is medically inadvisable for a participant to attempt to achieve the targeted cholesterol count), the plan will make available a reasonable alternative standard that takes the relevant medical condition into account. In addition, all plan materials describing the terms of the program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.'' Individual *D* is unable to achieve a cholesterol count under 200. The plan accommodates *D* by making the discount available to *D,* but only if *D* complies with a low-cholesterol diet.

(ii) *Conclusion.* In this *Example 4,* the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve the targeted count (or for whom it is medically inadvisable to attempt to achieve the targeted count) in the prescribed period by providing a reasonable alternative standard. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium discount does not violate this section.

Example 5. (i) *Facts.* A group health plan will waive the $250 annual deductible (which is less than [10/15/20] percent of the annual cost of employee-only coverage under the plan) for the following year for participants who have a body mass index between 19 and 26, determined shortly before the beginning of the year. However, any participant for whom it is unreasonably difficult due to a medical condition to attain this standard (and any participant for whom it is medically inadvisable to attempt to achieve this standard) during the plan year is given the same discount if the participant walks for 20 minutes three days a week. Any participant for whom it is unreasonably difficult due to a medical condition to attain either standard (and any participant for whom it is medically inadvisable to attempt to achieve either standard during the year) is given the same discount if the individual satisfies a reasonable alternative standard that is tailored to the individual's situation. All plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a body mass index between 19 and 26 (or if it is medically inadvisable for you to attempt to achieve this body mass index) this year, your deductible will be waived if you walk for 20 minutes three days a week. If you cannot follow the walking program, call us at the number above and we will work with you to develop another way to have your deductible waived, such as a dietary regimen.''

(ii) *Conclusion.* In this *Example 5,* the program is a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it generally accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve (or for whom it is medically inadvisable to attempt to achieve) the targeted body mass index by providing a reasonable alternative standard (walking) and it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to walk by providing an alternative standard that is reasonable for the individual. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard for every individual. Thus, the waiver of the deductible does not violate this section.

Example 6. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a form for participants to certify that they have not used tobacco products in the preceding twelve months. Participants who do not provide the certification are assessed a surcharge that is [10/15/20] percent of the cost of employee-only coverage. However, all plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a health factor for you to meet the requirements under this program (or if it is medically inadvisable for you to attempt to meet the requirements of this program), we will make available a reasonable alternative standard for you to avoid this surcharge.'' It is unreasonably difficult for Individual *E* to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates *E* by requiring *E* to participate in a smoking cessation program to avoid the surcharge. *E* can avoid the surcharge for as long as *E* participates in the program, regardless of whether *E* stops smoking (as long as *E* continues to be addicted to nicotine).

(ii) *Conclusion.* In this *Example 6,* the premium surcharge is permissible as a bona fide wellness program because it satisfies the four requirements of this paragraph (f). First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote good health or prevent disease. Third, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to quit using tobacco products by providing a reasonable alternative standard. Fourth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium surcharge does not violate this section.

* * * * *

Dated: June 22, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: August 29, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 01–107 Filed 1–5–01; 8:45 am]

BILLING CODE 4120–01–P; 4510–29–P; 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–114082–00]

RIN 1545–AY32

HIPAA Nondiscrimination

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: Elsewhere in this issue of the **Federal Register**, the IRS is issuing temporary and final regulations governing the provisions prohibiting discrimination based on a health factor for group health plans. The IRS is issuing the temporary and final regulations at the same time that the Pension and Welfare Benefits Administration of the U.S. Department of Labor and the Health Care Financing Administration of the U.S. Department of Health and Human Services are issuing substantially similar interim final regulations governing the provisions prohibiting discrimination based on a health factor for group health plans and issuers of health insurance coverage offered in connection with a group health plan under the Employee Retirement Income Security Act of 1974 and the Public Health Service Act. The temporary regulations provide guidance to employers and group health plans relating to the group health plan nondiscrimination requirements. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written comments and requests for a public hearing must be received by April 9, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–114082–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered to: CC:M&SP:RU (REG–114082–00), room 5226, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at: *http://www.irs.gov/tax_regs/regslist.html.*

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Russ Weinheimer at 202–622–6080; concerning submissions of comments or requests for a hearing, Sonya Cruse at 202–622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information referenced in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

The collections of information are in § 54.9802–1T (see the temporary regulations published elsewhere in this issue of the **Federal Register**). The collections of information are required so that individuals denied enrollment in a group health plan based on one or more health factors will be apprised of their right to enroll in the plan without regard to their health. The likely respondents are business or other for-profit institutions, nonprofit institutions, small businesses or organizations, and Taft-Hartley trusts. Responses to this collection of information are required of plans that have denied enrollment to individuals based on one or more health factors.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S:O, Washington, DC 20224. Comments on the collection of information should be received by April 9, 2001. Comments are specifically requested concerning:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;
- The accuracy of the estimated burden associated with the proposed collection of information (see the preamble to the temporary regulations published elsewhere in this issue of the **Federal Register**);
- How to enhance the quality, utility, and clarity of the information to be collected;
- How to minimize the burden of complying with the proposed collection of information, including the application of automated collection techniques or other forms of information technology; and
- Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Background

The temporary regulations published elsewhere in this issue of the **Federal Register** add a new § 54.9802–1T to the Miscellaneous Excise Tax Regulations.[1] When these proposed regulations are published as final regulations, they will supplement the final regulations in § 54.9802–1 being published elsewhere in this issue of the **Federal Register**. The proposed, temporary, and final regulations are being published as part of a joint rulemaking with the Department of Labor and the Department of Health and Human Services (the joint rulemaking).

Special Analyses

This regulation is not subject to the Unfunded Mandates Reform Act of 1995 because the regulation is an interpretive regulation. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation. For further information and for analyses relating to the joint rulemaking, see the preamble to the joint rulemaking. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. Comments are specifically requested on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Russ Weinheimer, Office of the Operating Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), IRS. However, other personnel from the IRS and Treasury Department participated in their development. The proposed regulations, as well as the temporary regulations, have been developed in coordination with personnel from the U.S. Department of Labor and the U.S. Department of Health and Human Services.

List of Subjects in 26 CFR Part 54

Excise taxes, Health insurance, Pensions, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 54.9802–1 is amended to read as follows:

[1] A previous § 54.9802–1T was published in the **Federal Register** on April 8, 1997. By operation of section 7805(e) of the Internal Revenue Code, the previous § 54.9802–1T expired on April 8, 2000. Proposed regulations containing the same text as previous § 54.9802–1T were also published on April 8, 1997, and final regulations based on those proposed regulations are being published elsewhere in this issue of the **Federal Register** as § 54.9802–1. The new § 54.9802–1T being published elsewhere in this issue of the **Federal Register** consists almost entirely of new guidance not contained in the previous § 54.9802–1T.

§ 54.9802–1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

[The text of this proposed amendments to this section is the same as the text of § 54.9802–1T published elsewhere in this issue of the **Federal Register**].

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–108 Filed 1–5–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–114083–00]

RIN 1545–AY33

Exception to the HIPAA Nondiscrimination Requirements for Certain Grandfathered Church Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance under section 9802(c) of the Internal Revenue Code relating to the exception for certain grandfathered church plans from the nondiscrimination requirements applicable to group health plans under section 9802(a) and (b). Final, temporary, and proposed regulations relating to the nondiscrimination requirements under section 9802(a) and (b) are being published elsewhere in this issue of the **Federal Register**. The regulations will generally affect sponsors of and participants in certain self-funded church plans that are group health plans, and the regulations provide plan sponsors and plan administrators with guidance necessary to comply with the law.

DATES: Written or electronic comments and requests for a public hearing must be received by April 9, 2001.

ADDRESSES: Send Submissions to: CC:M&SP:RU (REG–114083–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–114083–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/tax_regs/regslist.html.*

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Russ Weinheimer at 202–622–6080; concerning submissions of comments or requests for a hearing, Sonya Cruse at 202–622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Miscellaneous Excise Tax Regulations (26 CFR part 54) relating to the exception for certain grandfathered church plans from the nondiscrimination requirements applicable to group health plans. The nondiscrimination requirements applicable to group health plans were added to the Internal Revenue Code (Code), in section 9802, by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191. HIPAA also added similar nondiscrimination provisions applicable to group health plans and health insurance issuers (such as health insurance companies and health maintenance organizations) under the Employee Retirement Income Security Act of 1974 (ERISA), administered by the U.S. Department of Labor, and the Public Health Service Act (PHS Act), administered by the U.S. Department of Health and Human Services.

Final and temporary regulations relating to the HIPAA nondiscrimination requirements in paragraphs (a) and (b) of section 9802 of the Code are being published elsewhere in this issue of the **Federal Register**. Those regulations are similar to, and have been developed in coordination with, interim final regulations also being published today by the Departments of Labor and Health and Human Services. Guidance under the HIPAA nondiscrimination requirements is summarized in a joint preamble to the final, interim final, and temporary regulations.

The exception for certain grandfathered church plans was added to section 9802, in a new subsection (c), by section 1532 of the Taxpayer Relief Act of 1997, Public Law 105–34. These proposed regulations would provide guidance for this exception. The guidance is summarized in the explanation below.

Explanation of Provisions

Church plans that are group health plans are generally subject to the Code provisions in Chapter 100 relating to access, portability, and renewability.[1] However, under section 9802(c), church plans satisfying certain requirements continuously since July 15, 1997 are not treated as failing to meet the section 9802 prohibitions against discrimination based on any health factor solely because the plan requires evidence of good health for the coverage of certain individuals.

The grandfather rule in section 9802(c) applies to a church plan for a plan year only if, on July 15, 1997 and at all times after that date before the beginning of the plan year, the church plan had provisions satisfying one of two alternative conditions. The first alternative condition is that the plan contain provisions requiring evidence of good health of two sets of individuals, that is, both (1) any employee of an employer with 10 or fewer employees and (2) any self-employed individual. The proposed regulations specify that this condition is not satisfied if the plan requires evidence of good health of only one of these sets of individuals. The proposed regulations also clarify that the plan provision for the first set of individuals must be exactly 10 or fewer. Thus, a plan provision requiring evidence of good health for employees of an employer of fewer than 10, or of greater than 10, employees does not satisfy this condition. For example, a plan provision requiring evidence of good health of any employee of an employer of five or fewer employees does not satisfy this condition.

The second alternative condition is that the plan contain provisions requiring evidence of good health of any individual who enrolls after the first 90 days of initial eligibility. The proposed regulations clarify that the period for these plan provisions must be exactly 90 days. Thus, a plan provision requiring evidence of good health of any individual who enrolls after the first 120 days of initial eligibility does not satisfy this condition.

The grandfather rule in section 9802(c) of the Code is not by its terms limited in its application to self-funded church plans. Section 2702 of the Public Health Service Act (PHS Act) imposes nondiscrimination requirements on health insurance issuers offering group health insurance coverage, and those nondiscrimination requirements are generally similar to the nondiscrimination requirements imposed on group health plans

[1] However, church plans are not subject to the similar requirements in Part 7 of Subtitle B of Title I of ERISA or to the similar requirements in Title XXVII of the PHS Act (except for health insurance coverage in connection with a church plan, as discussed below).

(including church plans) under paragraphs (a) and (b) of section 9802 of the Code. However, section 2702 of the PHS Act does not include an exception for health insurance issuers offering group health insurance coverage to church plans comparable to the exception for church plans in section 9802(c) of the Code. Thus, if a church plan providing benefits through group health insurance coverage were to require evidence of good health of certain individuals as permitted under section 9802(c) of the Code, the requirement of evidence of good health would cause the health insurance issuer providing the coverage to violate the nondiscrimination requirements of the PHS Act. In such a case, the sanctions under the PHS Act would apply to the issuer, but those under the Code would not apply to the church plan. Thus, assuming that group health insurance coverage complies with the nondiscrimination requirements of the PHS Act, the rule in section 9802(c) of the Code is, in effect, available only to church plans that are not funded through group health insurance because only such church plans do not include insurance coverage that is subject to Title XXVII of the PHS Act. Accordingly, the examples in the proposed regulations illustrating situations where section 9802(c) is available are limited to group health plans that are not funded through group health insurance in order to avoid misleading insured church plans about the availability of the grandfather rule in section 9802(c).

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information requirement on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments that are submitted timely (a signed original and eight (8) copies) to the IRS. Comments are specifically requested on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Russ Weinheimer, Office of the Operating Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended in part by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Section 54.9802–2 also issued under 26 U.S.C. 9802. * * *

Par. 2. Section 54.9802–2 is added to read as follows:

§ 54.9802–2 Special rules for certain church plans.

(a) *Exception for certain church plans*—(1) *Church plans in general.* A church plan described in paragraph (b) of this section is not treated as failing to meet the requirements of section 9802 or §§ 54.9802–1 and 54.9802–1T solely because the plan requires evidence of good health for coverage of individuals under plan provisions described in paragraph (b)(2) or (3) of this section.

(2) *Health insurance issuers.* See sections 2702 and 2721(b)(1)(B) of the Public Health Service Act (42 U.S.C. 300gg–2 and 300gg–21(b)(1)(B)) and 45 CFR 146.121, which require health insurance issuers providing health insurance coverage under a church plan that is a group health plan to comply with nondiscrimination requirements similar to those that church plans are required to comply with under section 9802 and §§ 54.9802–1 and 54.9802–1T except that those nondiscrimination requirements do not include an exception for health insurance issuers comparable to the exception for church plans under section 9802(c) and this section.

(b) *Church plans to which this section applies*—(1) *Church plans with certain coverage provisions in effect on July 15, 1997.* This section applies to any church plan (as defined in section 414(e)) for a plan year if, on July 15, 1997 and at all times thereafter before the beginning of the plan year, the plan contains either the provisions described in paragraph (b)(2) of this section or the provisions described in paragraph (b)(3) of this section.

(2) *Plan provisions applicable to individuals employed by employers of 10 or fewer employees and self-employed individuals*—(i) A plan contains the provisions described in this paragraph (b)(2) if it requires evidence of good health of both—

(A) Any employee of an employer of 10 or fewer employees (determined without regard to section 414(e)(3)(C), under which a church or convention or association of churches is treated as the employer); and

(B) Any self-employed individual.

(ii) A plan does not contain the provisions described in this paragraph (b)(2) if the plan contains only one of the provisions described in this paragraph (b)(2). Thus, for example, a plan that requires evidence of good health of any self-employed individual, but not of any employee of an employer with 10 or fewer employees, does not contain the provisions described in this paragraph (b)(2). Moreover, a plan does not contain the provision described in paragraph (b)(2)(i)(A) of this section if the plan requires evidence of good health of any employee of an employer of fewer than 10 (or greater than 10) employees. Thus, for example, a plan does not contain the provision described in paragraph (b)(2)(i)(A) of this section if the plan requires evidence of good health of any employee of an employer with five or fewer employees.

(3) *Plan provisions applicable to individuals who enroll after the first 90 days of initial eligibility*—(i) A plan contains the provisions described in this paragraph (b)(3) if it requires evidence of good health of any individual who enrolls after the first 90 days of initial eligibility under the plan.

(ii) A plan does not contain the provisions described in this paragraph (b)(3) if it provides for a longer (or shorter) period than 90 days. Thus, for example, a plan requiring evidence of good health of any individual who enrolls after the first 120 days of initial eligibility under the plan does not contain the provisions described in this paragraph (b)(3).

(c) *Examples.* The rules of this section are illustrated by the following examples:

Example 1. (i) Facts. A church organization maintains two church plans for entities affiliated with the church. One plan is a group health plan that provides health coverage to all employees (including ministers and lay workers) of any affiliated church entity that has more than 10 employees. The other plan is Plan *O*, which is a group health plan that is not funded through insurance coverage and that provides health coverage to any employee (including ministers and lay workers) of any affiliated church entity that has 10 or fewer employees and any self-employed individual affiliated with the church (including a self-employed minister of the church). Plan *O* requires evidence of good health in order for any individual of a church entity that has 10 or fewer employees to be covered and in order for any self-employed individual to be covered. On July 15, 1997 and at all times thereafter before the beginning of the plan year, Plan *O* has contained all the preceding provisions.

(ii) *Conclusion.* In this Example 1, because Plan *O* contains the plan provisions described in paragraph (b)(2) of this section and because those provisions were in the plan on July 15, 1997 and at all times thereafter before the beginning of the plan year, Plan *O* will not be treated as failing to meet the requirements of section 9802, § 54.9802–1, or § 54.9802–1T for the plan year solely because the plan requires evidence of good health for coverage of the individuals described in those plan provisions.

Example 2. (i) *Facts.* A church organization maintains Plan *P,* which is a church plan that is not funded through insurance coverage and that is a group health plan providing health coverage to individuals employed by entities affiliated with the church and self-employed individuals affiliated with the church (such as ministers). On July 15, 1997 and at all times thereafter before the beginning of the plan year, Plan *P* has required evidence of good health for coverage of any individual who enrolls after the first 90 days of initial eligibility under the plan.

(ii) *Conclusion.* In this *Example 2,* because Plan *P* contains the plan provisions described in paragraph (b)(3) of this section and because those provisions were in the plan on July 15, 1997 and at all times thereafter before the beginning of the plan year, Plan *P* will not be treated as failing to meet the requirements of section 9802, § 54.9802–1, or § 54.9802–1T for the plan year solely because the plan requires evidence of good health for coverage of individuals enrolling after the first 90 days of initial eligibility under the plan.

(d) *Effective date.* [Reserved]

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–109 Filed 1–5–01; 8:45 am]

BILLING CODE 4830–01–P

Federal Register

Monday,
January 8, 2001

Part III

Department of Education

Rehabilitation Services Administration
Recreational Program; Notice

DEPARTMENT OF EDUCATION

RIN 1820–ZA12

Rehabilitation Services Administration Recreational Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed priority for fiscal year (FY) 2001 and later years.

SUMMARY: The Assistant Secretary for the Office of Special Education and Rehabilitative Services proposes a priority under the Recreational Program. The Assistant Secretary may use this priority for competitions in FY 2001 and later years. We take this action to provide individuals with disabilities recreational activities and related experiences to aid in their employment, mobility, socialization, independence, and community integration.

DATES: We must receive your comments on or before February 7, 2001.

ADDRESSES: Address all comments about this proposed priority to Mary E. Chambers, U.S. Department of Education, 400 Maryland Avenue, SW., room 3320, Switzer Building, Washington, DC 20202–2649. If you prefer to send your comments through the Internet, use the following address:

Mary_Chambers@ed.gov

You must include the term ''Recreational Program'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Mary E. Chambers. Telephone: (202) 205–8435 or via Internet:

Mary_Chambers@ed.gov

If you use a telecommunications device for the deaf (TDD) you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION:

Invitation To Comment

We invite you to submit comments regarding this proposed priority. We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further opportunities we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this proposed priority in room 3420, Switzer Building, 330 C Street SW., Washington, DC, between the hours of 9 a.m. and 4:30 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed priority. If you want to schedule an appointment for this type of aid, you may call (202) 205–8113 or (202) 260–9895. If you use a TDD, you may call the Federal Information Relay Service at 1–800–877–8339.

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing or funding additional priorities, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which the Assistant Secretary chooses to use this proposed priority, we invite applications through a notice in the **Federal Register**.

Priority

Background

Authority for the Recreational Program is contained in section 305 of the Rehabilitation Act of 1973, as amended (the Act) (29 U.S.C. 775). This proposed priority would support projects that provide individuals with disabilities with recreational activities and experiences that aid in their employment, mobility, socialization, independence, and community integration.

Proposed Priority

Under 34 CFR 75.105(c)(3) the Assistant Secretary proposes to give an absolute preference to applications that meet the following priority. The Assistant Secretary proposes to fund under this competition only applications that meet this absolute priority.

Projects must provide recreational services to individuals with disabilities. Recreational services include, but are not limited to, vocational skills development, leisure education, leisure networking, leisure resource development, physical education and sports, scouting and camping, 4-H activities, music, dancing, handicrafts, art, and homemaking. Recreational services do not include the construction of facilities for aquatic rehabilitation therapy.

Projects must provide recreational services to individuals with disabilities in settings with peers who are not individuals with disabilities.

Statutory Requirements

All applicants seeking funding under this competition must—

(a) Describe the manner in which the applicant will address the needs of individuals with disabilities from minority backgrounds (section 21(c) of the Act);

(b) Describe the manner in which the findings and results of the project to be funded under the grant, particularly information that facilitates the replication of the results of that project, will be made generally available (section 305(a)(4)(A) of the Act);

(c) Demonstrate ways in which recreational activities assist in maximizing the independence and integration of individuals with disabilities into community-based recreational programs (section 305(a)(1)(C) of the Act);

(d) Assure that the project will maintain, at a minimum, the same level of services over the three-year project period (section 305(a)(5) of the Act);

(e) Assure that the service program funded under the grant will be continued after Federal assistance ends (section 305(a)(4)(B) of the Act); and

(f) Provide non-Federal resources (in cash or in-kind) to pay the non-Federal share cost of the project in year two at 25 percent of year one Federal grant and year three at 50 percent of year one Federal grant (section 305(a)(3)(B) of the Act).

National Education Goals

The eight National Education Goals focus the Nation's education reform efforts and provide a framework for improving teaching and learning.

This proposed priority would address the National Education Goal that every American will possess the knowledge and skills necessary to compete in a global economy

Executive Order 12866

This notice of proposed priority has been reviewed in accordance with Executive Order 12866. Under the terms of the order the Assistant Secretary has

assessed the potential costs and benefits of this regulatory action.

The potential costs associated with the notice of proposed priority are those resulting from statutory requirements and those we have determined as necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of this notice of proposed priority, we have determined that the benefits of the proposed priority justify the costs.

We have also determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Elsewhere in this notice we discuss the potential costs and benefits of this proposed priority under the following heading: Background.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news.html

To use PDF you must have Adobe Acrobat Reader, which is available free at either of the preceding sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at:

http://www.access.gpo.gov/nara/index.html

Program Authority: 29 U.S.C. 775.

(Catalog of Federal Domestic Assistance Number: 84.128J Recreational Program.)

Dated: December 1, 2000.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 01–407 Filed 1–5–01; 8:45 am]

BILLING CODE 4000–01–U

Federal Register

Monday,
January 8, 2001

Part IV

Department of Transportation

Federal Highway Administration

23 CFR Parts 655 and 940
Intelligent Transportation System Architecture and Standards; Final Rule

Federal Transit Administration

Federal Transit Administration National ITS Architecture Policy on Transit Projects; Notice

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 655 and 940

[FHWA Docket No. FHWA–99–5899]

RIN 2125–AE65

Intelligent Transportation System Architecture and Standards

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The purpose of this document is to issue a final rule to implement section 5206(e) of the Transportation Equity Act for the 21st Century (TEA–21), enacted on June 9, 1998, which required Intelligent Transportation System (ITS) projects funded through the highway trust fund to conform to the National ITS Architecture and applicable standards. Because it is highly unlikely that the entire National ITS Architecture would be fully implemented by any single metropolitan area or State, this rule requires that the National ITS Architecture be used to develop a local implementation of the National ITS Architecture, which is referred to as a ''regional ITS architecture.'' Therefore, conformance with the National ITS Architecture is defined under this rule as development of a regional ITS architecture within four years after the first ITS project advancing to final design, and the subsequent adherence of ITS projects to the regional ITS architecture. The regional ITS architecture is based on the National ITS Architecture and consist of several parts including the system functional requirements and information exchanges with planned and existing systems and subsystems and identification of applicable standards, and would be tailored to address the local situation and ITS investment needs.

EFFECTIVE DATE: February 7, 2001.

FOR FURTHER INFORMATION CONTACT: *For technical information:* Mr. Bob Rupert, (202) 366–2194, Office of Travel Management (HOTM–1) and Mr. Michael Freitas, (202) 366–9292, ITS Joint Program Office (HOIT–1). *For legal information:* Mr. Wilbert Baccus, Office of the Chief Counsel (HCC–32), (202) 366–1346, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Docket Management System (DMS) at: *http//dmses.dot.gov/submit.* Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text Format (RTF), American Standard Code Information Interchange (ASCII) (TXT), Portable Document Format (PDF), and WordPerfect (version 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the web site.

An electronic copy of this document may be downloaded by using a computer, modem, and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may also reach the Office of the **Federal Register**'s home page at *http://www.nara.gov/fedreg* and the Government Printing Office's web page at: *http://www.access.gpo.gov/nara.* The document may also be viewed at the DOT's ITS web page at *http://www.its.dot.gov.*

Background

A notice of proposed rulemaking (NPRM) concerning this rule was published at 65 FR 33994 on May 25, 2000, and an extension of the comment period to September 23, 2000, was published at 65 FR 45942 on July 26, 2000.

In the NPRM on this rule, the FHWA had proposed that the regional ITS architecture follow from the ITS integration strategy proposed in another NPRM entitled ''Statewide Transportation Planning; Metropolitan Transportation Planning'' published at 65 FR 33922 on May 25, 2000. That rule is being developed according to a different schedule and will be issued separately. For this reason, all references to the proposed integration strategy have been removed from this rule. However, it is still the intent of this rule that regional ITS architectures be based on established, collaborative transportation planning processes. The other major changes to the final rule relate to options for developing a regional ITS architecture and the time allowed to develop such an architecture. Additional changes to the final rule largely deal with clarification of terms, improved language dealing with staging and grandfathering issues, and clarification of use of ITS standards.

Intelligent Transportation Systems represent the application of information processing, communications technologies, advanced control strategies, and electronics to the field of transportation. Information technology in general is most effective and cost beneficial when systems are integrated and interoperable. The greatest benefits in terms of safety, efficiency, and costs are realized when electronic systems are systematically integrated to form a whole in which information is shared with all and systems are interoperable.

In the transportation sector, successful ITS integration and interoperability require addressing two different and yet fundamental issues; that of technical and institutional integration. *Technical integration* of electronic systems is a complex issue that requires considerable up-front planning and meticulous execution for electronic information to be stored and accessed by various parts of a system. *Institutional integration* involves coordination between various agencies and jurisdictions to achieve seamless operations and/or interoperability.

In order to achieve effective institutional integration of systems, agencies and jurisdictions must agree on the benefits of ITS and the value of being part of an integrated system. They must agree on roles, responsibilities, and shared operational strategies. Finally, they must agree on standards and, in some cases, technologies and operating procedures to ensure interoperability. In some instances, there may be multiple standards that could be implemented for a single interface. In this case, agencies will need to agree on a common standard or agree to implement a technical translator that will allow dissimilar standards to interoperate. This coordination effort is a considerable task that will happen over time, not all at once. Transportation organizations, such as, transit properties, State and local transportation agencies, and metropolitan planning organizations must be fully committed to achieving institutional integration in order for integration to be successful. The transportation agencies must also coordinate with agencies for which transportation is a key, but not a primary part of their business, such as, emergency management and law enforcement agencies.

Successfully dealing with both the technical and institutional issues requires a high-level conceptual view of the future system and careful, comprehensive planning. The framework for the system is referred to as the *architecture.* The architecture defines the system components, key functions, the organizations involved, and the type of information shared

between organizations and parts of the system. The architecture is, therefore, fundamental to successful system implementation, integration, and interoperability.

Additional background information may be found in docket number FHWA–99–5899.

The National ITS Architecture

The Intermodal Surface Transportation Efficiency Act of 1991, Public Law 102–240, 105 Stat. 1914, initiated Federal funding for the ITS program. The program at that time was largely focused on research and development and operational tests of technologies. A key part of the program was the development of the National ITS Architecture. The National ITS Architecture provides a common structure for the design of ITS systems. The architecture defines the functions that could be performed to satisfy user requirements and how the various elements of the system might connect to share information. It is not a system design, nor is it a design concept. However, it does define the framework around which multiple design approaches can be developed, each one specifically tailored to meet the needs of the user, while maintaining the benefits of a common approach.

The National ITS Architecture, Version 3.0 can be obtained from the ITS Joint Program Office of the DOT in CD–ROM format and on the ITS web site *http://www.its.dot.gov*. The effort to develop a common national system architecture to guide the evolution of ITS in the United States over the next 20 years and beyond has been managed since September 1993 by the DOT. The National ITS Architecture describes in detail what types of interfaces should exist between ITS components and how they will exchange information and work together to deliver the given ITS user service requirements.

The National ITS Architecture and standards can be used to guide multi-level government and private-sector business planners in developing and deploying nationally compatible systems. By ensuring system compatibility, the DOT hopes to accelerate ITS integration nationwide and develop a strong, diverse marketplace for related products and services.

It is highly unlikely that the entire National ITS Architecture will be fully implemented by any single metropolitan area or State. For example, the National ITS Architecture contains information flows for an Automated Highway System that is unlikely to be part of most regional implementations. However, the National ITS Architecture has considerable value as a framework for local governments in the development of regional ITS architectures by identifying the many functions and information sharing opportunities that may be desired. It can assist local governments with both of the key elements: technical interoperability and institutional coordination.

The National ITS Architecture, because it aids in the development of a high-level conceptual view of a future system, can assist local governments in identifying applications that will support their future transportation needs. From an institutional coordination perspective, the National ITS Architecture helps local transportation planners to identify other stakeholders who may need to be involved and to identify potential integration opportunities. From a technical interoperability perspective, the National ITS Architecture provides a logical and physical architecture and process specifications to guide the design of a system. The National ITS Architecture also identifies interfaces where standards may apply, further supporting interoperability.

Transportation Equity Act for the 21st Century

As noted above, section 5206(e) of the TEA–21, Public Law 105–178, 112 Stat. 457, requires ITS projects funded from the highway trust fund to conform to the National ITS Architecture, applicable or provisional standards, and protocols. One of the findings of Congress in section 5202 of the TEA–21, is that continued investment in systems integration is needed to accelerate the rate at which ITS is incorporated into the national surface transportation network. Two of the purposes of the ITS program, noted in section 5203(b) of the TEA–21, are to expedite the deployment and integration of ITS, and to improve regional cooperation and operations planning for effective ITS deployment. Use of the National ITS Architecture provides significant benefits to local transportation planners and deployers as follows:

1. The National ITS Architecture provides assistance with technical design. It saves considerable design time because physical and logical architectures are already defined.

2. Information flows and process specifications are defined in the National ITS Architecture, allowing local governments to accelerate the process of defining system functionality.

3. The architecture identifies standards that will support interoperability now and into the future, but it leaves selection of technologies to local decisionmakers.

4. The architecture provides a sound engineering framework for integrating multiple applications and services in a region.

ITS Architecture and Standards NPRM

Discussion of Comments

The FHWA received 105 comments on this docket from a wide range of stakeholders, including major industry associations, State departments of transportation, Metropolitan Planning Organizations (MPOs), and local agencies. The comments were generally favorable about the scope and content, but requested additional clarification and guidance on implementation of specific items. On many issues, some commenters wanted more specific requirements, while others wanted more flexibility. Most commenters, including major industry associations and public sector agencies, agreed with the overall scope, but some felt that the specifics might be difficult to implement and asked for clarification of key terms. A few commenters wanted the FHWA to reduce the number of requirements or convert the rulemaking into a guidance activity until more ITS deployment experience is gained.

In summary, the FHWA received a large number of generally favorable comments about the NPRM that suggested minor specific changes and expressed a need for further guidance on implementation. Since the general tenor of the comments was positive, the FHWA has kept the scope of the NPRM and made appropriate clarifications to the text of the final rule to address concerns raised in comments. In response to the many comments requesting it, starting in early 2001, the FHWA will also provide a program of guidance, training, and technical support to assist with the implementation of this rule. The following is a detailed discussion of the comments and their disposition, organized by subject matter.

Section 940.3 Definitions

ITS Project. There were 34 comments submitted to the docket concerning the definition of an ITS project. Many of the commenters felt the definition was not clear enough, was too broad, or was too subject to interpretation. Some comments questioned how much of a project's budget would have to be spent on ITS before a project would be considered an ITS project. Some suggested specific language to more narrowly define an ITS project by

focusing on the portion of the overall project that is actually ITS or by suggesting language that would narrow the definition of an ITS project to only include projects which introduce new or changed integration opportunities.

Since the intent of this rule and the supporting legislation is to facilitate the deployment of integrated ITS systems, it is the position of the FHWA that the definition of an ITS project must be fairly broad to include any ITS system being funded with highway trust fund dollars. It is only by properly considering all planned ITS investments in the development of a regional ITS architecture that the integration opportunities and needs can even be identified. This consideration should be carried out in the development of an architecture prior to the specific project being advanced. If, in the development of a regional ITS architecture, it is determined that a specific planned project offers no real integration opportunities for the region, then the impact of this rule on that specific project is minimal.

As a response to the comments concerning the clarity of the definition, the definition of an ITS project has been slightly modified to remove the examples since they were considered misleading. The FHWA recognizes that any definition will be subject to interpretation by the stakeholders and acknowledges the need for guidance in this area to ensure clear and consistent interpretation of this rule. Guidance on what constitutes an ITS project (including examples) will be developed to assist the various stakeholders, including the FHWA Division Offices, to better understand what projects should be considered ITS projects.

Region. There were 26 comments submitted related to the definition of a region. Seven comments supported the open definition provided in the NPRM, arguing that the possible integration opportunities in an area should define the region and that there were too many possible variations to allow a restrictive definition. Six commenters who expressed concern over varying conditions interpreted the definition to mean Metropolitan Planning Area (MPA). Five comments suggested an MPA was too restrictive. Eight other comments indicated that the proposed definition of a region did not clearly identify what entity would have the lead in developing a regional ITS architecture or thought the definition implied the MPO should have the lead. Nine comments suggested various limits or boundaries to fit specific situations. Ten comments expressed a need for greater clarification of the definition for a region.

The intent of the proposed definition was to allow considerable flexibility on the part of the stakeholders in defining the boundaries of a region to best meet their identified integration opportunities. While there was no intent to generally restrict the definition to MPAs or States, the FHWA determined that regional ITS architectures should be based on an integration strategy that was developed by an MPO or State as part of its transportation planning process.

Given that the final rule does not require or reference an integration strategy, the FHWA feels a need to provide more specific guidance on the definition of a region. As such, the definition of a region has been revised to indicate that the MPA should be the minimum area considered when establishing the boundaries of a region for purposes of developing a regional ITS architecture within a metropolitan area. This should not be interpreted to mean that a region must be an MPA, or no less than an MPA, but the MPA and all the agencies and jurisdictions within the MPA should be at least considered for inclusion in the process of developing a regional ITS architecture within a metropolitan area. This rule is silent on other possible limits or minimum areas for defining a region, relying on the flexible nature of this rule to accommodate those special circumstances. The FHWA also acknowledges it is possible that overlapping regions could be defined and overlapping regional ITS architectures be developed to meet the needs of the regions.

Other Definitions. There were 20 comments suggesting that other terms used in the NPRM be defined. These included ''interoperability,'' ''standards,'' ''concept of operations,'' ''conceptual design,'' and ''integration strategy.'' Several of these are no longer used in the final rule and, therefore, were not defined. Other terms, such as ''interoperability'' and ''standards,'' were determined to be common terms whose definition did not effect the implementation of the final rule. Furthermore, language regarding standards conformity has been clarified in the body of the final rule.

Section 940.5 Policy

Twenty-eight commenters addressed the issue of consistency between the two related FHWA notices of proposed rulemaking (23 CFR parts 940 and 1410) and the Federal Transit Administration's (FTA) notice (FTA Docket No. FTA–99–6417) on National ITS Architecture published at 65 FR 34002 on May 25, 2000. The comments revealed a lack of understanding about the relationship between the regional ITS architecture and the integration strategy proposed as part of the revisions to FHWA's transportation planning rules. There were five comments suggesting a single DOT rule addressing how all ITS projects would meet the National ITS Architecture conformance requirements of the TEA–21 instead of an FHWA rule for highway projects and an FTA policy for transit projects. Four other comments acknowledged the need for two policies, but recommended they articulate the same process.

A final transportation planning rule is being developed on a different schedule than this rule, and comments regarding the portions of the National ITS Architecture conformity process included in the transportation planning rule will be addressed as it proceeds toward issuance. The FHWA and FTA have chosen to go forward with policies that have been developed cooperatively to implement the National ITS Architecture conformance process. This FHWA rule and the parallel FTA policy have been developed without reference to the proposed changes to the transportation planning process, including no mention of the development of an integration strategy. However, the policy statement of this rule notes a link to established transportation planning processes, as provided under 23 CFR part 450. This rule fully supports these collaborative methods for establishing transportation goals and objectives, and does not provide a mechanism for introducing projects outside of the transportation planning processes.

This final rule on National ITS Architecture conformance and the FTA policy on the same subject have been developed cooperatively and coordinated among the agencies to ensure compatible processes. Any differences between this rule and the parallel FTA policy are intended to address differences in highway and transit project development and the way the FHWA and the FTA administer projects and funds.

Fifteen commenters questioned the need for an integration strategy, and the relationship between the strategy and the regional ITS architecture.

Given the fact that proposed revisions to the FHWA's transportation planning rules are being developed according to a different schedule, this rule has been revised to remove any references to an integration strategy. Comments regarding the integration strategy will be addressed in the final transportation

planning rule, and the discussion of the regional ITS architecture in § 940.9 has been revised to clarify its content.

Section 940.7 Applicability

A few commenters noted that the proposed rule had not addressed the TEA–21 language that allows for the Secretary to authorize certain exceptions to the conformity provision. These exceptions relate to those projects designed to achieve specific research objectives or, if three stated criteria are met, to those intended to upgrade or expand an ITS system in existence on the date of enactment of the TEA–21. The legislation also included a general exemption for funds used strictly for operations and maintenance of an ITS system in existence on the date of enactment of the TEA–21.

The FHWA acknowledges this omission and has included the appropriate language in this section of the rule.

Section 940.9 Regional ITS Architecture

Several comments were received related to the way the proposed rule referred to developing regional ITS architectures. Eight comments, from State agencies and metropolitan planning organizations, supported an incremental approach to developing regional ITS architectures, starting with project ITS architectures and building them together. Four other comments, from metropolitan planning organizations and industry associations, noted that an ad hoc regional ITS architecture developed incrementally through projects would result in an architecture less robust than if there were a single, initial effort to develop it.

Also, thirteen comments from the Association of American State Highway and Transportation Officials (AASHTO) and a number of States recommended extending the time for developing regional ITS architectures, as the proposed two year implementation would be too short. Ten of the commenters preferred four years in order to acquire the necessary resources for developing regional ITS architectures.

Most commenters were in agreement with the content of the regional ITS architecture as defined in the proposed rule. However, there were 19 comments that dealt with confusion over the definition of both ''conceptual design'' and ''concept of operations.'' In addition, there were 17 other comments on the makeup of the stakeholders, involvement of the private sector, and the need and desirability of ''agreements'' between stakeholders.

The comments indicated confusion regarding the development of regional ITS architectures, and especially so in discussing the period of time for their development. Therefore, the final rule has clarified the time period for developing regional ITS architectures by adopting the proposed extension to four years subsequent to beginning to deploy ITS projects (§ 940.9(c)), or four years from the effective date of this rule for those areas that are currently deploying ITS projects (§ 940.9(b)). In clarifying the time for development, this rule has eliminated any references to specific methods for developing regional ITS architectures. By not prescribing any methods, the rule provides flexibility to a region in deciding how it should develop its regional ITS architecture. Guidance and information related to developing regional ITS architectures is available from FHWA Division Offices and from the ITS web site, *http://www.its.dot.gov*, and will be expanded to provide assistance in meeting the intent of the rule.

Both the terms ''conceptual design'' and ''concept of operations'' have been deleted from the final rule. In their stead are descriptions of the content that is expected to form the basis for a regional ITS architecture. This content has not significantly changed from that defined in the NPRM but is now contained in § 940.9(d). The level of detail required is to the architecture flow level as defined in the National ITS Architecture. The regional ITS architecture must identify how agencies, modes, and systems will interact and operate if the architecture is to fulfill the objective of promoting ITS integration within a region.

The relevant stakeholders for a region will vary from region to region. The list articulated in § 940.9(a) is representative only and not meant to be inclusive or exclusive. On the specific issue of private sector participation, if the private sector is deploying ITS systems in a region or otherwise providing an ITS-based service, it would be appropriate to engage them in the development of a regional ITS architecture. Because of these variations from region to region, the FHWA felt it inappropriate to attempt to define an all inclusive list of stakeholders. The group of relevant stakeholders will be a function of how the region is defined and how transportation services are provided to the public. Section 940.9(d)(4) specifies that in the development of the regional ITS architecture, it shall include ''any agreements (existing or new) required for operations.'' The formalization of these types of agreements is at the discretion of the region and participating stakeholders.

There were 14 comments from a broad range of organizations questioning how existing regional ITS architectures, strategic plans or ITS Early Deployment Plans would be treated under this rule. It is the intent of the FHWA that any existing ITS planning documents should be used to the extent practical to meet the requirements of this rule. If a regional ITS architecture is in place, is up to date, and addresses all the requirements of a regional ITS architecture as described in this rule, there is no requirement to develop a ''new'' one. If the existing regional ITS architecture does not address all the requirements of the rule, it may be possible to update it so that it meets the regional ITS architecture requirements of this rule. What is necessary is that the end result is an architecture that meets the requirements of this rule and properly addresses the ITS deployments and integration opportunities of that region. This issue is specifically addressed in § 940.9(e) of this rule.

There were five comments related to the impact of this rule on legacy systems (*i.e.*, ITS systems already in place) and requesting some sort of ''grandfathering'' for them. The language in § 940.11(g) of the final rule clarifies the grandfathering or staging aspects of the process. The final rule does not require any changes or modifications to existing systems to conform to the National ITS Architecture. It is very likely that a regional ITS architecture developed by the local agencies and other stakeholders would call for changes to legacy systems over time to support desired integration. However, such changes would not be required by the FHWA; they would be agreed upon by the appropriate stakeholders as part of the development of the regional ITS architecture.

There were 15 comments dealing with the maintenance process and status of the National ITS Architecture. Two comments suggested the need for the FHWA to formally adopt the National ITS Architecture. Four other comments also supported the formalization of a process for maintaining or updating it with the full opportunity for public input.

Conformance with the National ITS Architecture is interpreted to mean the use of the National ITS Architecture to develop a regional ITS architecture, and the subsequent adherence of all ITS projects to that regional ITS architecture. This rule requires that the National ITS Architecture be used as a resource in developing a regional ITS architecture.

As a technical resource, it is important that the National ITS Architecture be maintained and updated as necessary in response to user input or to add new user services, but formal adoption of the National ITS Architecture is not necessary. However, the FHWA recognizes the need to maintain the National ITS Architecture and to establish an open process for configuration control that includes public participation. The process currently used by the DOT to maintain the National ITS Architecture is very rigorous and involves significant public participation. That process is currently being reviewed by the DOT with the intent of establishing a configuration management process that engages the public at key stages and ensures a consensus for updating the National ITS Architecture.

Four comments suggested that this rule should not be implemented until the National ITS Architecture was complete. The National ITS Architecture will never stop evolving since there always is a potential need to regularly update it as more is learned about ITS deployment. The FHWA believes the National ITS Architecture is developed to a stage where it can be used as a resource in developing regional ITS architectures, as required by this rule.

Seventeen comments asked the FHWA to define the agency that is responsible for the development and maintenance of the regional ITS architecture; specifically MPOs and/or the State as those entities that are already responsible for the planning process.

The FHWA did not define the responsibility for either creating or maintaining the regional ITS architecture to a specific entity because of the diversity of transportation agencies and their roles across the country. It is recognized that in some regions traditional State and MPO boundaries may not meet the needs of the traveling public or the transportation community. This is also why the FHWA did not rigidly define a region. The FHWA encourages MPOs and States to include the development of their regional ITS architectures as part of their transportation planning processes. However, the decision is best left to the region to determine the approach that best reflects their needs, as indicated in § 940.9. It is clear that the value of a regional ITS architecture will only be realized if that architecture is maintained through time. However, in accepting Federal funds under title 23, U.S.C., the State is ultimately responsible for complying with Federal requirements, as provided in 23 U.S.C. 106 and 133.

Four commenters noted that the proposed rule did not adequately address planning for, or committing to, a defined level of operations and maintenance.

The final rule addresses this concern on two primary levels, in the development of the regional ITS architecture and the development of individual projects. Section 940.9(d)(4) specifies that in the development of the regional ITS architecture, it shall include ''any agreements (existing or new) required for operations.'' The formalization of these types of agreements is at the discretion of the region and participating stakeholders.

Also, relative to operations and management at a project level, § 940.11(c)(7) specifies that the systems engineering analysis (required of all ITS projects) includes ''procedures and resources necessary for the operations and management of the system.''

Section 940.11 Project Implementation

In addition to the comments on regional ITS architecture development noted above, the docket received 86 comments on systems engineering and project implementation. These comments revealed that the structure of the NPRM in discussing regional ITS architecture development, project systems engineering analysis, and project implementation was confusing and difficult to read.

To clarify these portions of the rule, the systems engineering and project implementation sections of the NPRM have been combined into § 940.11, Project Implementation. Also, paragraphs that were in the regional ITS architecture section of the NPRM that discussed major ITS projects and the requirements for developing project level ITS architectures have been rewritten to clarify their applicability. Since these paragraphs deal with project development issues, they have been moved to § 940.11(e). A definition for ''project level ITS architecture'' was added in § 940.3 and a description of its contents provided in § 940.11(e).

The docket received 33 comments regarding systems engineering and the systems engineering analysis section of the proposed rule. Most of the comments related to the definition, the process not being necessary except for very large projects, and confusion as to how these requirements relate to existing FHWA policy.

In response to the docket comments, the definition of systems engineering in § 940.3 has been clarified and is more consistent with accepted practice. In order to provide consistency in the regional ITS architecture process, the systems engineering analysis detailed in §§ 940.11(a) through 940.11(c) must apply to all ITS projects regardless of size or budget. However, the analysis should be on a scale commensurate with project scope. To allow for the greatest flexibility at the State and local level, in § 940.11(c), a minimum number of elements have been clearly identified for inclusion in the systems engineering analysis. Many of those elements are currently required as provided in 23 CFR 655.409, which this rule replaces. Recognizing the change in some current practices this type of analysis will require, the FHWA intends to issue guidance, training, and technical support in early 2001 to help stakeholders meet the requirements of the final rule.

Fifty-three comments were submitted regarding ITS standards and interoperability tests. The commenters expressed concern about requiring the use of ITS standards and interoperability tests prematurely, the impact on legacy systems of requiring ITS standards, and confusion regarding the term ''adopted by the DOT.''

In response to the comments, the FHWA has significantly modified the final rule to eliminate reference to the use of standards and interoperability tests prior to adoption in § 940.11(f). Section 940.11(g) addresses the applicability of standards to legacy systems. It is not the intent of the DOT to formally adopt any standard before the standard is mature; and also, not all ITS standards should, or will, be formally adopted by the DOT. Formal adoption of a standard means that the DOT will go through the rulemaking process, including a period of public comment, for all standards that are considered candidates for adoption.

The DOT has developed a set of criteria to determine when a standard could be considered for formal adoption. These criteria include, at a minimum, the following elements:

1. The standard has been approved by a Standard Development Organization (SDO).

2. The standard has been successfully tested in real world applications as appropriate.

3. The standard has received some degree of acceptance by the community served by the standard.

4. Products exist to implement the standard.

5. There is adequate documentation to support the use of the standard.

6. There is training available in the use of the standard where applicable.

Therefore, the intent of the rule is to require the use of a standard only when these criteria have been met, and there has been a separate rulemaking on adoption of the standard.

The only interoperability tests that are currently contemplated by the DOT are those associated with the Commercial Vehicle Operations (CVO) program. These tests are currently being used by States deploying CVO systems and will follow a similar set of criteria for adoption as those defined for standards.

Section 940.13 Project Administration

There were nine comments related to how conformity with the final rule would be determined, and by whom. There were 11 comments about how conformity with the regional ITS architecture would be determined, and by whom. Six comments specifically suggested methods for determining conformance, including a process similar to current Federal planning oversight procedures. Six other commenters suggested that determination be made by the MPO or State. For either case, the comments reflected a lack of clarity as to what documentation would be necessary. There were six related comments suggesting the level of documentation be commensurate with the scale of the planned ITS investments in the region.

In § 940.13 of the final rule, the FHWA has attempted to clarify the process for determining conformance. Conformance of an ITS project with a regional ITS architecture shall be made prior to authorization of funding for project construction or implementation as provided in 23 U.S.C. 106 and 133. We do not intend to create new oversight procedures beyond those provided in 23 U.S.C. 106 and 133, but in those cases where oversight and approval for ITS projects is assumed by the State, the State will be responsible for ensuring compliance with this regulation and the FHWA's oversight will be through existing processes.

There were 14 comments concerning the documentation requirements of the proposed rule and generally suggesting they be reduced. Certainly the development of a regional ITS architecture and evidence of conformance of a specific project to that regional ITS architecture implies some level of documentation be developed. However, to allow flexibility on the part of the State or local agency in demonstrating compliance with the final rule, no specific documentation is required to be developed or submitted to the FHWA for review or approval. The FHWA recognizes the need to be able to scale the regional ITS architecture and the associated documentation to the needs of the region. Section 940.9(a) of the final rule contains specific language allowing such scaling.

Summary of Requirements

I. The Regional ITS Architecture

This final rule on the ITS Architecture and Standards requires the development of a local implementation of the National ITS Architecture referred to as a regional ITS architecture. The regional ITS architecture is tailored to meet local needs, meaning that it does not address the entire National ITS Architecture and can also address services not included in the National ITS Architecture. The regional ITS architecture shall contain a description of the region and the identification of the participating agencies and other stakeholders; the roles and responsibilities of the participating agencies and other stakeholders; any agreements needed for operation; system functional requirements; interface requirements and information exchanges with planned and existing systems; identification of applicable standards; and the sequence of projects necessary for implementation. Any changes made in a project design that impact the regional ITS architecture shall be identified and the appropriate revisions made and agreed to in the regional ITS architecture.

Any region that is currently implementing ITS projects shall have a regional ITS architecture within four years of the effective date of this rule. All other regions not currently implementing ITS projects shall have a regional ITS architecture within four years of the first ITS project for that region advancing to final design. In this context, a region is a geographical area that is based on local needs for sharing information and coordinating operational strategies among multiple projects. A region can be specified at a metropolitan, Statewide, multi-State, or corridor level. Within a metropolitan area, the metropolitan planning area should be the minimum area that is considered when establishing the boundaries of a region for purposes of developing a regional ITS architecture. A regional approach promotes integration of transportation systems. The size of the region should reflect the breadth of the integration of transportation systems.

II. Project Development

Additionally, this rule requires that all ITS projects be developed using a systems engineering analysis. All ITS projects that have not yet advanced to final design are required to conform to the system engineering requirements in § 940.11 upon the effective date of this rule. Any ITS project that has advanced to final design by the effective date of this rule is exempt from the requirements of § 940.11. When the regional ITS architecture is completed, project development will be based on the relevant portions of it which the project implements. Prior to completion of the regional ITS architecture, major ITS projects will develop project level ITS architectures that are coordinated with the development of the regional ITS architecture. ITS projects will be required to use applicable ITS standards and interoperability tests that have been officially adopted by the DOT. Where multiple standards exist, it will be the responsibility of the stakeholders to determine how best to achieve the interoperability they desire.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of the Department of Transportation's regulatory policies and procedures. It is anticipated that the economic impact of this rulemaking will be minimal. This determination is based upon preliminary and final regulatory assessments prepared for this action that indicate that the annual impact of the rule will not exceed $100 million nor will it adversely affect the economy, a sector of the economy, productivity, jobs, the environment, public health, safety, or State, local, or tribal governments. In addition, the agency has determined that these changes will not interfere with any action taken or planned by another agency and will not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. Copies of the preliminary and final regulatory assessments are included in the docket.

Costs

The FHWA prepared a preliminary regulatory evaluation (PRE) for the NPRM and comments were solicited. That analysis estimated the total costs of this rule over 10 years to be between $38.1 million and $44.4 million (the net present value over 10 years was between $22.3 million and $31.2 million). The annual constant dollar impact was estimated to range between $3.2 million and $4.4 million. We believe that the

cost estimates as stated in the PRE are negligible. The FHWA received only one comment in response to the PRE. That commenter, the Capital District Transportation Committee of Albany, New York suggested that our cost estimates were too low, but provided no further detail or rationale which would cause us to reconsider or increase our cost estimates in the initial regulatory evaluation.

These 10-year cost estimates set forth in the PRE included transportation planning cost increases, to MPOs ranging from $10.8 million to $13.5 million, and to States from $5.2 million to $7.8 million associated with our initial requirement to develop an ITS integration strategy that was proposed as part of the metropolitan and statewide planning rulemaking effort. The agency now plans to advance that proposed ITS integration strategy in the planning rule on a different time schedule than this final rule. Thus, the costs originally set forth in the PRE for the ITS integration strategy have been eliminated from the final cost estimate in the final regulatory evaluation (FRE) for this rule.

In the FRE, the agency estimates the cost of this rule to be between $1 million an $16 million over ten years, which are the estimated costs of this rule to implementing agencies for the development of the regional ITS architectures. These costs do not include any potential additional implementation costs for individual projects which are expected to be minimal and were extremely difficult to estimate. Thus, the costs to the industry are less than that originally estimated in the agency's NPRM.

Benefits

In the PRE, the FHWA indicated that the non-monetary benefits derived from the proposed action included savings from the avoidance of duplicative development, reduced overall development time, and earlier detection of potential incompatibilities. We stated that, as with project implementation impacts, the benefits of the rule are very difficult to quantify in monetary terms. Thus, we estimated that the coordination guidance provided through implementation of the rule could provide savings of approximately $150,000 to any potential entity seeking to comply with the requirements of section 5206(e) of the TEA–21 as compared with an entity having to undertake compliance individually. The costs may be offset by benefits derived from the reduction of duplicative deployments, reduced overall development time, and earlier detection of potential incompatibilities.

In developing a final regulatory evaluation for this action, we did not denote a significant change in any of the benefits anticipated by this rule. This is so notwithstanding the fact that our planning costs for the ITS integration strategy have been eliminated from the final cost estimate. The primary benefits of this action that result from avoidance of duplicative development, reduced overall development time, and earlier detection of potential incompatibilities will remain the same.

In sum the agency believes that the option chosen in this action will be most effective at helping us to implement the requirements of section 5206(e) of the TEA–21. In developing the rule, the FHWA has sought to allow broad discretion to those entities impacted, in levels of response and approach that are appropriate to particular plans and projects, while conforming to the requirements of the TEA–21. The FHWA has considered the costs and benefits of effective implementation of ITS through careful and comprehensive planning. Based upon the information above, the agency anticipates that the economic impact associated with this rulemaking action is minimal and a full regulatory evaluation is not necessary.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated, through the regulatory assessment, the effects of this action on small entities and has determined that this action will not have a significant economic impact on a substantial number of small entities. Small businesses and small organizations are not subject to this rule, which applies to government entities only. Since § 940.9(a) of this rule provides for regional ITS architectures to be developed on a scale commensurate with the scope of ITS investment in the region, and § 940.11(b) provides for the ITS project systems engineering analysis to be on a scale commensurate with the project scope, compliance requirements will vary with the magnitude of the ITS requirements of the entity. Small, less complex ITS projects have correspondingly small compliance documentation requirements, thereby accommodating the interest of small government entities. Small entities, primarily transit agencies, are accommodated through these scaling provisions that impose only limited requirements on small ITS activities. For these reasons, the FHWA certifies that this action will not have a significant impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This action does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). This rule will not result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.

Executive Order 13132 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and the FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this action does not preempt any State law or State regulation or affect the State's ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway planning and construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act of 1995

This action does not contain information collection requirements for the purposes of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

We have analyzed this action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

Executive Order 12630 (Taking of Private Property)

This rule does not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Government Actions and Interference with Constitutionally Protected Property Rights.

National Environmental Policy Act

The agency has analyzed this action for the purposes of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321–4347), and has determined that this action will not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this proposed action with the Unified Agenda.

List of Subjects

23 CFR Part 655

Design standards, Grant programs-transportation, Highways and roads, Incorporation by reference, Signs and symbols, Traffic regulations.

23 CFR Part 940

Design standards, Grant programs-transportation, Highways and roads, Intelligent transportation systems.

Issued on: January 2, 2001.

Kenneth R. Wykle,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA amends Chapter I of title 23, Code of Federal Regulations, as set forth below:

PART 655—[AMENDED]

1. The authority citation for part 655 continues to read as follows:

Authority: 23 U.S.C. 101(a), 104, 109(d), 114(a), 217, 315, and 402(a); 23 CFR 1.32, and 49 CFR 1.48(b).

Subpart D—[Removed and reserved]

2. Remove and reserve subpart D of part 655, consisting of §§ 655.401, 655.403, 655.405, 655.407, 655.409, 655.411.

3. Add a new subchapter K, consisting of part 940, to read as follows:

Subchapter K—Intelligent Transportation Systems

PART 940—INTELLIGENT TRANSPORTATION SYSTEM ARCHITECTURE AND STANDARDS

Sec.
940.1 Purpose.
940.3 Definitions.
940.5 Policy.
940.7 Applicability.
940.9 Regional ITS architecture.
940.11 Project implementation.
940.13 Project administration.

Authority: 23 U.S.C. 101, 106, 109, 133, 315, and 508; sec 5206(e), Public Law 105–178, 112 Stat. 457 (23 U.S.C. 502 note); and 49 CFR 1.48.

§ 940.1 Purpose.

This regulation provides policies and procedures for implementing section 5206(e) of the Transportation Equity Act for the 21st Century (TEA–21), Public Law 105–178, 112 Stat. 457, pertaining to conformance with the National Intelligent Transportation Systems Architecture and Standards.

§ 940.3 Definitions.

Intelligent Transportation System (ITS) means electronics, communications, or information processing used singly or in combination to improve the efficiency or safety of a surface transportation system.

ITS project means any project that in whole or in part funds the acquisition of technologies or systems of technologies that provide or significantly contribute to the provision of one or more ITS user services as defined in the National ITS Architecture.

Major ITS project means any ITS project that implements part of a regional ITS initiative that is multi-jurisdictional, multi-modal, or otherwise affects regional integration of ITS systems.

National ITS Architecture (also ''national architecture'') means a common framework for ITS interoperability. The National ITS Architecture comprises the logical architecture and physical architecture which satisfy a defined set of user services. The National ITS Architecture is maintained by the United States Department of Transportation (DOT) and is available on the DOT web site at *http://www.its.dot.gov.*

Project level ITS architecture is a framework that identifies the institutional agreement and technical integration necessary to interface a major ITS project with other ITS projects and systems.

Region is the geographical area that identifies the boundaries of the regional ITS architecture and is defined by and based on the needs of the participating agencies and other stakeholders. In metropolitan areas, a region should be no less than the boundaries of the metropolitan planning area.

Regional ITS architecture means a regional framework for ensuring institutional agreement and technical integration for the implementation of ITS projects or groups of projects.

Systems engineering is a structured process for arriving at a final design of a system. The final design is selected from a number of alternatives that would accomplish the same objectives and considers the total life-cycle of the project including not only the technical merits of potential solutions but also the costs and relative value of alternatives.

§ 940.5 Policy.

ITS projects shall conform to the National ITS Architecture and standards in accordance with the requirements contained in this part. Conformance with the National ITS Architecture is interpreted to mean the use of the National ITS Architecture to develop a regional ITS architecture, and the subsequent adherence of all ITS projects to that regional ITS architecture. Development of the regional ITS architecture should be consistent with the transportation planning process for Statewide and Metropolitan Transportation Planning.

§ 940.7 Applicability.

(a) All ITS projects that are funded in whole or in part with the highway trust fund, including those on the National Highway System (NHS) and on non-NHS facilities, are subject to these provisions.

(b) The Secretary may authorize exceptions for:

(1) Projects designed to achieve specific research objectives outlined in the National ITS Program Plan under section 5205 of the TEA–21, or the Surface Transportation Research and Development Strategic Plan developed under 23 U.S.C. 508; or

(2) The upgrade or expansion of an ITS system in existence on the date of enactment of the TEA–21, if the Secretary determines that the upgrade or expansion:

(i) Would not adversely affect the goals or purposes of Subtitle C (Intelligent Transportation Systems Act of 1998) of the TEA–21;

(ii) Is carried out before the end of the useful life of such system; and

(iii) Is cost-effective as compared to alternatives that would meet the conformity requirement of this rule.

(c) These provisions do not apply to funds used for operations and maintenance of an ITS system in existence on June 9, 1998.

§ 940.9 Regional ITS architecture.

(a) A regional ITS architecture shall be developed to guide the development of ITS projects and programs and be consistent with ITS strategies and projects contained in applicable transportation plans. The National ITS Architecture shall be used as a resource in the development of the regional ITS architecture. The regional ITS architecture shall be on a scale commensurate with the scope of ITS investment in the region. Provision should be made to include participation from the following agencies, as appropriate, in the development of the regional ITS architecture: Highway agencies; public safety agencies (*e.g.,* police, fire, emergency/medical); transit operators; Federal lands agencies; State motor carrier agencies; and other operating agencies necessary to fully address regional ITS integration.

(b) Any region that is currently implementing ITS projects shall have a regional ITS architecture by February 7, 2005.

(c) All other regions not currently implementing ITS projects shall have a regional ITS architecture within four years of the first ITS project for that region advancing to final design.

(d) The regional ITS architecture shall include, at a minimum, the following:

(1) A description of the region;

(2) Identification of participating agencies and other stakeholders;

(3) An operational concept that identifies the roles and responsibilities of participating agencies and stakeholders in the operation and implementation of the systems included in the regional ITS architecture;

(4) Any agreements (existing or new) required for operations, including at a minimum those affecting ITS project interoperability, utilization of ITS related standards, and the operation of the projects identified in the regional ITS architecture;

(5) System functional requirements;

(6) Interface requirements and information exchanges with planned and existing systems and subsystems (for example, subsystems and architecture flows as defined in the National ITS Architecture);

(7) Identification of ITS standards supporting regional and national interoperability; and

(8) The sequence of projects required for implementation.

(e) Existing regional ITS architectures that meet all of the requirements of paragraph (d) of this section shall be considered to satisfy the requirements of paragraph (a) of this section.

(f) The agencies and other stakeholders participating in the development of the regional ITS architecture shall develop and implement procedures and responsibilities for maintaining it, as needs evolve within the region.

§ 940.11 Project implementation.

(a) All ITS projects funded with highway trust funds shall be based on a systems engineering analysis.

(b) The analysis should be on a scale commensurate with the project scope.

(c) The systems engineering analysis shall include, at a minimum:

(1) Identification of portions of the regional ITS architecture being implemented (or if a regional ITS architecture does not exist, the applicable portions of the National ITS Architecture);

(2) Identification of participating agencies roles and responsibilities;

(3) Requirements definitions;

(4) Analysis of alternative system configurations and technology options to meet requirements;

(5) Procurement options;

(6) Identification of applicable ITS standards and testing procedures; and

(7) Procedures and resources necessary for operations and management of the system.

(d) Upon completion of the regional ITS architecture required in §§ 940.9(b) or 940.9(c), the final design of all ITS projects funded with highway trust funds shall accommodate the interface requirements and information exchanges as specified in the regional ITS architecture. If the final design of the ITS project is inconsistent with the regional ITS architecture, then the regional ITS architecture shall be updated as provided in the process defined in § 940.9(f) to reflect the changes.

(e) Prior to the completion of the regional ITS architecture, any major ITS project funded with highway trust funds that advances to final design shall have a project level ITS architecture that is coordinated with the development of the regional ITS architecture. The final design of the major ITS project shall accommodate the interface requirements and information exchanges as specified in this project level ITS architecture. If the project final design is inconsistent with the project level ITS architecture, then the project level ITS architecture shall be updated to reflect the changes. The project level ITS architecture is based on the results of the systems engineering analysis, and includes the following:

(1) A description of the scope of the ITS project;

(2) An operational concept that identifies the roles and responsibilities of participating agencies and stakeholders in the operation and implementation of the ITS project;

(3) Functional requirements of the ITS project;

(4) Interface requirements and information exchanges between the ITS project and other planned and existing systems and subsystems; and

(5) Identification of applicable ITS standards.

(f) All ITS projects funded with highway trust funds shall use applicable ITS standards and interoperability tests that have been officially adopted through rulemaking by the DOT.

(g) Any ITS project that has advanced to final design by February 7, 2001 is exempt from the requirements of paragraphs (d) through (f) of this section.

§ 940.13 Project administration.

(a) Prior to authorization of highway trust funds for construction or implementation of ITS projects, compliance with § 940.11 shall be demonstrated.

(b) Compliance with this part will be monitored under Federal-aid oversight procedures as provided under 23 U.S.C. 106 and 133.

[FR Doc. 01–391 Filed 1–5–01; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Federal Transit Administration National ITS Architecture Policy on Transit Projects

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The Federal Transit Administration (FTA) announces the FTA National ITS Architecture Policy on Transit Projects, which is defined in this document. The National ITS Architecture Policy is a product of statutory changes made by the Transportation Equity Act for the 21st Century (TEA–21) (Pub. L. 105–178) enacted on June 9, 1998. The National ITS Architecture Policy is also a product of the Request for Comment on the National ITS Architecture Consistency Policy for Project Development that was published in the **Federal Register** on May 25, 2000. Because it is highly unlikely that the entire National ITS Architecture would be fully implemented by any single metropolitan area or State, this policy requires that the National ITS Architecture be used to develop a local implementation of the National ITS Architecture, which is referred to as a ''regional ITS architecture.'' Therefore, conformance with the National ITS Architecture is defined under this policy as development of a regional ITS architecture within four years after the first ITS project advancing to final design, and the subsequent adherence of ITS projects to the regional ITS architecture. The regional ITS architecture is based on the National ITS Architecture and consists of several parts including the system functional requirements and information exchanges with planned and existing systems and subsystems and identification of applicable standards, and would be tailored to address the local situation and ITS investment needs.

DATE: *Effective Date:* This policy is effective from February 7, 2001.

ADDRESSES: For FTA staff, Federal Transit Administration, Department of Transportation (DOT), 400 Seventh Street, SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: *For Technical Information:* Ron Boenau, Chief, Advanced Public Transportation Systems Division (TRI–11), at (202) 366–0195 or Brian Cronin, Advanced Public Transportation Systems Division (TRI–11), at (202) 366–8841. *For Legal Information:* Richard Wong, Office of the Chief Council (202) 366–1936. The policy is posted on the FTA website on the Internet under http://www.fta.dot.gov.

Electronic Access: An electronic copy of this document may be downloaded using a computer, modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register's home page at: *http://www.nara.gov/fedreg* and the Government Printing Office's web page at: *http://www.access.gpo.gov/nara.*

Internet users may access all comments received by the U.S. DOT Dockets, Room PL–401, for the Request for Comment that was issued on May 25, 2000 which were used to clarify this Policy, by using the universal resource locator (URL): *http://dms.dot.gov.* It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help. The docket number for the Request for Comment was FTA–99–6417.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Transit Administration (FTA) published a Request for Comment on May 25, 2000, to implement section 5206(e) of the Transportation Equity Act for the 21st Century (TEA–21) (Pub.L. 105–178), which was enacted on June 9, 1998.

Section 5206(e) of TEA–21 requires that the Secretary of the DOT must

> Ensure that intelligent transportation system projects carried out using funds made available from the Highway Trust Fund, * * * conform to the national architecture, applicable standards or provisional standards, and protocols developed under subsection(a).

The objectives for the FTA's National ITS Architecture Policy for Transit Projects are to:

- Provide requirements for ITS project development for projects implemented wholly or partially with highway trust funds.
- Achieve system integration of ITS projects funded through the highway trust fund with other transportation projects planned for the region, which will thereby enable electronic information and data sharing for advanced management and operations of the ITS infrastructure.
- Engage stakeholders (state DOT's, transit agencies, public safety agencies, other transportation operating agencies) in the project development and implementation process.
- Facilitate future expansion capability of the ITS infrastructure.
- Save design time through use of the National ITS Architecture requirements definitions and market packages.

FTA has developed this policy to meet the TEA–21 requirement contained in Section 5206(e) and the DOT/FTA goal to encourage effective deployment of ITS projects. Additionally, DOT and FTA encourage the coordination of local ITS strategies and projects to help meet national and local goals for mobility, accessibility, safety, security, economic growth and trade, and the environment.

The National ITS Architecture documents were developed by the US DOT, and are updated on an as-needed basis. Current work to update the National ITS Architecture is the Archive Data User Service, which provides the ability to store and process data over an extended period of time. FTA is pursuing the addition of a Rail ITS program for travel management, vehicles, and users. New versions of the documents, when they are issued, will be available from the US DOT on the DOT website at *www.its.dot.gov.* Version 3.0 is the latest version of the National ITS Architecture.

The first section of this policy contains a complete analysis of and response to the comments provided to the docket. The remainder of the Notice contains the FTA National ITS Architecture Policy for Transit Projects.

II. Public Comments

Eighteen comments were submitted to the FTA National ITS Architecture Consistency Policy for Project Development docket by the September 23, 2000, close of the comment period. Comments were submitted by transit operators (3), state and local governments (5), metropolitan planning organizations (4), industry associations (3), and consultants (3). As indicated earlier, a complete analysis and response to the docket comments is provided. In order to facilitate focused comments, FTA asked a series of questions about the policy. The public comment section is organized first by analysis and response to the specific questions asked; second by responses to comments not specifically related to one of the nine questions; and finally by an explanation of other changes. In general, the comments received were positive. Therefore, the FTA has kept the scope of the policy and made appropriate clarifications to the text of the policy to address concerns raised in comments. In response to the many comments requesting it, the FTA, in association with the ITS Joint Program Office, in the Federal Highway Administration (FHWA) will also provide a program of guidance, training, and technical

support to assist with the implementation of this policy.

Questions

1. Do reviewers understand the definition of a major ITS investment as defined in Section IV, ''Regional ITS Architecture,'' or is more clarification needed, and if so please explain?

Comments: Nine commenters submitted responses to this question. In general, commenters found the definition confusing, and did not understand why major ITS projects need to be called out over other ITS projects. One commenter noted that small dollar projects can have a major impact on future development, while an expensive system may have no impact. Another commenter was unclear about the term ''supporting national interoperability.''

Response: Of specific concern to the agency is the timing in which requirements for this policy are enacted. As such, the terms ''major ITS investment'' and ''major ITS project'' were provided so as to distinguish between projects that will require immediate correlation to the regional ITS architecture and those that do not. The term ''major ITS investment'' was also found to be redundant to ''major ITS project'' and was removed from the policy. Guidance on the classification of ''ITS projects'' and ''major ITS projects'' will be provided upon enactment of the policy.

2. Do reviewers understand the definition of an ITS project, or is more clarification needed, and if so please explain?

Comments: Nine commenters submitted responses to this question. Commenters found this term less confusing than ''major ITS investments,'' but requested more clarification. Some commenters proposed alternative language or asked for clarification on particular examples.

Response: The agency has clarified the definition by deleting the potentially ambiguous examples provided and will develop guidance material that provides examples of projects that will be considered ITS projects and those that will not be considered ITS projects. In general, unless a technology project is implementing one of the ITS user services defined in the National ITS Architecture, it would not be considered an ITS project.

3. Do reviewers understand the difference between a ''major ITS investment,'' and an ''ITS project'', or is more clarification needed, and if so please explain?

Comments: Eight commenters submitted responses to this question. Commenters had mixed responses, as some commenters found the differences to be clear, while others requested that guidance material be provided to further explain the differences. Commenters did suggest that a ''project'' is a ''project'' and should not be quantified in terms of dollar amounts.

Response: As described in the response to question 1, the agency has removed the term ''major ITS investment'' and will provide guidance on the term ''ITS project.''

4. Are the requirements for development of a Regional ITS Architecture clear? If not, what is not clear about the requirement?

Comment: Nine commenters provided responses to the question. Most commenters found the requirements to be unclear and/or did not agree with the requirements. One commenter suggested that a region will have different definitions. One commenter noted that a concept of operations and conceptual design are normally conducted at the project level. One commenter requested clarification as to the appropriate place to program projects, in the regional ITS architecture, or in the planning process.

Response: Of specific concern to the agency is providing a flexible policy that allows the transportation stakeholders to define their region and the roles and responsibilities of each stakeholder during the development of a regional ITS architecture. As such, the agency has clarified the requirements of a regional ITS architecture and also removed the specific requirements for a Concept of Operations and a Conceptual Design. Instead, the agency has listed the specific requirements for a regional ITS architecture and has left the development, documentation, and maintenance of the regional ITS architecture to the stakeholders involved. Also, the region is defined as ''a geographical area that is based on local needs for sharing information and coordinating operational strategies among multiple projects.'' A region can be specified at a metropolitan, Statewide, multi-State, or corridor level. Additional guidance on this topic will be provided after enactment of the policy.

5. What additional guidance, if any, is required to explain how to implement this proposed policy?

Comments: Ten commenters provided responses to this question. All the comments called for additional guidance on the specifics of implementing this policy. Commenters requested guidance on the definition of a ''region,'' the ownership of the regional ITS architecture, determination of stakeholders, regional ITS architecture maintenance, certification and simplification of definitions. One commenter requested that the policy be limited to only the ITS Integration Requirements defined in the Metropolitan and Statewide Planning NPRM.

Response: The agency will provide guidance materials to address the comments suggested. The ITS Integration Strategy, as defined in the NPRM, is part of the planning process and as such does not satisfactorily address project level requirements.

6. The proposed rule allows regions to develop a Regional Architecture as a separate activity, or incrementally, as major ITS investments are developed within a region. Do reviewers anticipate particular difficulties with implementing and documenting either approach?

Comments: Nine commenters provided responses to this question. Commenters largely did not favor one approach over the other. One commenter suggested that a regional ITS architecture with a twenty year time horizon is impractical and infeasible. One commenter suggested that either approach would require additional staff resources.

Response: The agency was concerned about the time horizon and development process needed to create a regional ITS architecture within the time period required and as a result suggested both an incremental and initial comprehensive approach. Based on the responses, the agency has modified the policy to be silent on the approach used to develop the regional ITS architecture. Instead, the agency focused on the products included in the regional ITS architecture, the effective date of the requirements, and the catalyst for requiring the development of a regional ITS architecture.

7. Do reviewers understand the relationships between the Integration Strategy, the Regional ITS Architecture, and the ITS Project Architecture?

Comment: Seven commenters provided a response to this question. In general, commenters did not understand the relationship between the Integration Strategy, regional ITS architecture, and the ITS Project Architecture. One commenter suggested that flexibility in application of project architecture must be maintained to accommodate legacy systems and to take advantage of technological innovation, while maintaining the outcome of interoperability, where applicable.

Response: The Agency is concerned with linkage between the planning process and the project development process. However, this policy only deals with the project level requirements.

Planning level requirements, including the Integration Strategy, will be explained as the Metropolitan and Statewide Planning Process rulemaking process is advanced. This policy only requires that the regional ITS architecture should be consistent with the transportation planning process. A definition for a project level ITS architecture has been added to the policy.

8. What additional guidance, if any, is required regarding phasing of this rule?

Comments: Six commenters submitted responses to this question. In general, the commenters stated that the phasing was clear. However, one commenter requested a three-year phase-in period. Several commenters requested that existing projects be exempt from the policy.

Response: The agency has clarified the policy statements that refer to the project status and the applicability of this policy. Projects that have reached final design by the date of this policy are exempt from the policy requirements. The agency has extended the time period for regional ITS architecture development to four years. Any region that is currently implementing ITS projects shall have a regional architecture within four years of the effective date of the final policy. All other regions not currently implementing ITS projects shall have a regional ITS architecture in place within four years of the first ITS project for that region advancing to final design.

9. Are the oversight and documentation requirements clear? If not, what is not clear about the requirements?

Comments: Eight commenters submitted responses to this question. Commenters in general requested more guidance from FTA on oversight and documentation requirements, but few provided suggestions to clarify the requirements. One commenter suggested that checklists to verify consistency requirements will be needed. Other commenters suggested that self-certification should be allowed, but also needs to be clearly defined.

Response: The agency will continue to use normal existing oversight procedures to review grantee compliance with FTA policies and regulations. Normal oversight procedures include the annual risk assessment of grantees performed by regional office staff, triennial reviews, planning process reviews, and project management oversight reviews, as applicable. In TEA–21, FTA was granted authority to use oversight funds to provide technical assistance to grantees in which oversight activities suggested non-compliance with agency policies and regulations. FTA is using oversight funds to specifically hire contractors with ITS experience who will monitor and assist grantees who are at risk of NOT meeting the National ITS Architecture Policy requirements. Additional guidance on oversight and documentation requirements will be provided.

Additional Comments

One commenter suggested that the proposed guidance circular requires that all of the agencies in a region agree before a project can be implemented, thus conferring ''veto'' power over the project. The agency does not intend for the policy to halt ITS deployment in areas where agencies cannot agree on project designs. As part of the regional ITS Architecture development, the agencies can agree to disagree, however, the regional ITS architecture should include a representation of the stand-alone ITS deployments.

One commenter suggests that the proposal infers that existing agreements between agencies will now need to be amended or redone, which would result in a halt in operations of successful ITS projects and prevent the completion of other ITS projects. In response to the comment, the agency has clarified the regional ITS architecture requirements to specify that existing agreements that address the regional ITS architecture requirements are sufficient and that new agreements are not necessarily required.

One commenter noted that a definition of ITS was not included in the policy. The commenter suggested that the definition provided in TEA–21 section 5206(e) should be included in the policy. The agency agrees and has added the definition of ITS to the list of definitions. However, the legislative definition of ITS is broad and other commenters have suggested that if the policy is written to include every new piece of electronics or hardware, then the policy would be too limiting. As a result, the policy is intended to apply only to projects meeting the definition of an ''ITS project'' listed in the ''Definitions'' section of the policy.

One commenter suggested that DOT should ensure that the Federal Highway Administration's (FHWA's) regulation and the FTA policy have the same statutory standing and that their requirements in ITS planning and deployment be consistent if not identical. The FTA and FHWA have different processes and procedures for project development. Therefore, the FHWA has issued a regulation, and FTA has issued the policy. The policy language in each document is consistent and will be carried out in a coordinated fashion, as applicable under FTA and FHWA project management and oversight procedures. FTA and FHWA planning procedures are a joint regulation and as such will be identical.

FTA received some comments regarding the use of standards. Several comments concern the premature use of required standards and interoperability tests, their impact on legacy systems, and confusion regarding the term ''adopted by the USDOT.''

In response to the comments, FTA has significantly modified the final policy to eliminate reference to the use of standards and interoperability tests prior to adoption through formal rulemaking. It is not the intent of the USDOT to formally adopt any standard before the standard is mature; also, not all ITS standards should, or will, be formally adopted by the USDOT. The only interoperability tests that are currently contemplated by the USDOT are those associated with the Commercial Vehicle Operations (CVO) program. These tests are currently being used by States deploying CVO systems and will follow a similar set of criteria for adoption as those defined for standards.

Other Changes

Several commenters expressed concern about linkages to the planning rule and the integration strategy. Comments regarding the portions of the National ITS Architecture conformity process included in the proposed transportation planning rule will be addressed as that rule proceeds to its issuance. The FHWA rule and the parallel FTA policy have been developed without direct reference to the proposed changes to the transportation planning process, including no mention of the development of an integration strategy. However, the policy statement of this guidance notes a link to transportation planning processes, and fully supports those collaborative methods for establishing transportation goals and objectives.

Policy Contents

I. Purpose
II. Definitions
III. Policy
IV. Applicability
V. Regional ITS Architecture
VI. Project Implementation
VII. Project Oversight
VIII. FTA Guidance

I. Purpose

This policy provides procedures for implementing section 5206(e) of the Transportation Equity Act for the 21st

Century, Public Law 105–178, 112 Stat. 547, pertaining to conformance with the National Intelligent Transportation Systems Architecture and Standards.

II. Definitions

Intelligent Transportation Systems (ITS) means electronics, communications or information processing used singly or in combination to improve the efficiency or safety of a surface transportation system.

ITS project means any project that in whole or in part funds the acquisition of technologies or systems of technologies that provide or significantly contribute to the provision of one or more ITS user services as defined in the National ITS Architecture.

Major ITS project means any ITS project that implements part of a regional ITS initiative that is multi-jurisdictional, multi-modal, or otherwise affects regional integration of ITS systems.

National ITS Architecture (also ''national architecture'') means a common framework for ITS interoperability. The National ITS Architecture comprises the logical architecture and physical architecture which satisfy a defined set of user services. The National ITS Architecture is maintained by U.S. DOT (Department of Transportation) and is available on the DOT web site at *http://www.its.dot.gov.*

Project level ITS architecture is a framework that identifies the institutional agreement and technical integration necessary to interface a major ITS project with other ITS projects and systems.

Region is the geographical area that identifies the boundaries of the regional ITS architecture and is defined by and based on the needs of the participating agencies and other stakeholders. A region can be specified at a metropolitan, Statewide, multi-State, or corridor level. In metropolitan areas, a region should be no less than the boundaries of the metropolitan planning area.

Regional ITS architecture means a regional framework for ensuring institutional agreement and technical integration for the implementation of ITS projects or groups of projects.

Systems engineering is a structured process for arriving at a final design of a system. The final design is selected from a number of alternatives that would accomplish the same objectives and considers the total life-cycle of the project including not only the technical merits of potential solutions but also the costs and relative value of alternatives.

III. Policy

ITS projects shall conform to the National ITS Architecture and standards in accordance with the requirements contained in this part. Conformance with the National ITS Architecture is interpreted to mean the use of the National ITS Architecture to develop a regional ITS architecture in support of integration and the subsequent adherence of all ITS projects to that regional ITS architecture. Development of the regional ITS architecture should be consistent with the transportation planning process for Statewide and Metropolitan Transportation Planning (49 CFR part 613 and 621).

IV. Applicability

(a) All ITS projects that are funded in whole or in part with the Highway Trust Fund (including the mass transit account) are subject to these provisions.

(b) The Secretary may authorize exceptions for:

1. Projects designed to achieve specific research objectives outlined in the National ITS Program Plan under section 5205 of the Transportation Equity Act for the 21st Century or the Surface Transportation Research and Development Strategic Plan developed under section 5208 of Title 23, United States Code; or

2. The upgrade or expansion of an ITS system in existence on the date of enactment of the Transportation Equity Act for the 21st Century if the Secretary determines that the upgrade or expansion—

a. Would not adversely affect the goals or purposes of Subtitle C (Intelligent Transportation Systems) of the Transportation Equity Act for the 21st Century and

b. Is carried out before the end of the useful life of such system; and

c. Is cost-effective as compared to alternatives that would meet the conformity requirement of this rule

(c) These provisions do not apply to funds used for Operations and Maintenance of an ITS system in existence on June 9, 1998.

V. Regional ITS Architecture

(a) A regional ITS architecture shall be developed to guide the development of ITS projects and programs and be consistent with ITS strategies and projects contained in applicable transportation plans. The National ITS Architecture shall be used as a resource in the development of the regional ITS architecture. The regional ITS architecture shall be on a scale commensurate with the scope of ITS investment in the region. Provision should be made to include participation from the following agencies, as appropriate, in the development of the regional ITS architecture: Highway agencies; public safety agencies (*e.g.,* police, fire, emergency/medical); transit agencies; federal lands agencies; state motor carrier agencies; and other operating agencies necessary to fully address regional ITS integration.

(b) Any region that is currently implementing ITS projects shall have a regional ITS architecture February 7, 2005.

(c) All other regions not currently implementing ITS projects shall have a regional ITS architecture within four years of the first ITS project for that region advancing to final design.

(d) The regional ITS architecture shall include, at a minimum, the following:

(1) A description of the region;

(2) Identification of participating agencies and other stakeholders;

(3) An operational concept that identifies the roles and responsibilities of participating agencies and stakeholders in the operation and implementation of the systems included in the regional ITS architecture;

(4) Any agreements (existing or new) required for operations, including at a minimum those affecting integration of ITS projects; interoperability of different ITS technologies, utilization of ITS-related standards, and the operation of the projects identified in the regional ITS architecture;

(5) System functional requirements;

(6) Interface requirements and information exchanges with planned and existing systems and subsystems (for example, subsystems and architecture flows as defined in the National ITS Architecture);

(7) Identification of ITS standards supporting regional and national interoperability;

(8) The sequence of projects required for implementation of the regional ITS architecture.

(e) Existing regional ITS architectures that meet all of the requirements of section V(d) shall be considered to satisfy the requirements of V(a).

(f) The agencies and other stakeholders participating in the development of the regional ITS architecture shall develop and implement procedures and responsibilities for maintaining the regional ITS architecture, as needs evolve within the region.

VI. Project Implementation

(a) All ITS projects funded with mass transit funds from the highway trust

fund shall be based on a systems engineering analysis.

(b) The analysis should be on a scale commensurate with the project scope.

(c) The systems engineering analysis shall include, at a minimum:

(1) Identification of portions of the regional ITS architecture being implemented (or if a regional ITS architecture does not exist, the applicable portions of the National ITS Architecture).

(2) Identification of participating agencies' roles and responsibilities;

(3) Requirements definitions:

(4) Analysis of alternative system configurations and technology options to meet requirements;

(5) Analysis of financing and procurement options;

(6) Identification of applicable ITS standards and testing procedures; and

(7) Procedures and resources necessary for operations and management of the system;

(d) Upon completion of the regional ITS architecture required in section V, the final design of all ITS projects funded with highway trust funds shall accommodate the interface requirements and information exchanges as specified in the regional ITS architecture. If the final design of the ITS project is inconsistent with the regional ITS architecture, then the regional ITS architecture shall be updated as per the process defined in V(f) to reflect the changes.

(e) Prior to completion of the regional ITS architecture, any major ITS project funded with highway trust funds that advances to final design shall have a project level ITS architecture that is coordinated with the development of the regional ITS architecture. The final design of the major ITS project shall accommodate the interface requirements and information exchanges as specified in this project level ITS architecture. If the project final design is inconsistent with the project level architecture, then the project level ITS architecture shall be updated to reflect the changes. The project level ITS architecture is based on results of the systems engineering analysis, and includes the following:

(1) A description of the scope of the ITS project

(2) An operational concept that identifies the roles and responsibilities of participating agencies and stakeholders in the operation and implementation of the ITS project;

(3) Functional requirements of the ITS project;

(4) Interface requirements and information exchanges between the ITS project and other planned and existing systems and subsystems; and

(5) Identification of applicable ITS standards

(b) All ITS projects funded with Mass Transit Funds from the Highway Trust Funds shall use applicable ITS standards and interoperability tests that have been officially adopted through rulemaking by the United States Department of Transportation (US DOT).

(c) Any ITS project that has advanced to final design by (effective date of policy) is exempt from the requirements of VI.

VII. Project Oversight

(a) Prior to authorization of Mass Transit Funds from the Highway Trust Fund for acquisition or implementation of ITS projects, grantees shall self-certify compliance with sections V and VI. Compliance with this policy shall be monitored under normal FTA oversight procedures, to include annual risk assessments, triennial reviews, and program management oversight reviews as applicable.

(b) Compliance with the following FTA Circulars shall also be certified:

- C5010.1C, Grant Management Guidelines
- C6100.1B, Application Instructions and Program Management Guidelines

VIII. FTA Guidance

FTA will develop appropriate guidance materials regarding the National ITS Architecture Consistency Policy.

Issued on: January 2, 2001.

Nuria I. Fernandez,

Acting Administrator.

[FR Doc. 01–392 Filed 1–5–01; 8:45 am]

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Monday,
January 8, 2001

Part V

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2001: Allocation for Metered Dose Inhalers and the Space Shuttle and Titan Rockets; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6929–6]

RIN 2060–AJ33

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2001: Allocation for Metered Dose Inhalers and the Space Shuttle and Titan Rockets

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this action, EPA is allocating essential use allowances for stratospheric ozone depleting substances for calendar year 2001. EPA allocates essential use allowances to an applicant for exempted production or import of a specific quantity of class I ozone depleting substances solely for the designated essential use. Essential use allowances permit a person to obtain controlled substances as an exemption to the January 1, 1996 regulatory phase-out of production and import of these substances. Today, EPA is allocating essential use allowances for the production and/or import of class I substances for use in medical devices for the treatment of asthma and chronic obstructive pulmonary disease, and for use in the Space Shuttle and Titan Rockets for calendar year 2001. With today's action, EPA is also amending the regulations to allow essential use allowances for medical devices to be transferred among essential use allowance holders. The essential use exemption for class I ODSs for laboratory and analytical applications will be addressed in a separate rulemaking.

DATES: This action is effective January 8, 2001.

ADDRESSES: Materials relevant to this rulemaking are contained in Docket No. A–93–39. The Docket phone is (202) 260–7548 and is located in Waterside Mall, Room M–1500, 401 M Street, SW., Washington, DC, 20460. The materials may be inspected from 8 a.m. until 5:30 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: The Stratospheric Ozone Protection Hotline at 1–800–296–1996 or Erin Birgfeld, U.S. Environmental Protection Agency, Global Programs Division, Office of Atmospheric Programs, 6205J, 1200 Pennsylvania Avenue N.W., Washington, DC, 20460; telephone (202) 564–9079; fax: (202) 565–2095; email: birgfeld.erin@epa.gov.

SUPPLEMENTARY INFORMATION:

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I. Background

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is the international agreement to reduce and eventually eliminate production and consumption[1] of all stratospheric ozone depleting substances (ODSs). As of January 1996, production and import of class I ODSs (except methyl bromide) were phased out in all developed countries, including the United States. However, the Protocol and the Clean Air Act (CAA or Act) provide exemptions that allow for the continued import and/or production of class I ODSs for specific uses. Under the Montreal Protocol, exemptions are granted for uses that are determined by the Parties to be ''essential'' as defined by Decision IV/25. The procedure set out by Decision IV/25 first calls for individual Parties to nominate essential uses. The Protocol's Technology and Economic Assessment Panel (TEAP or the Panel) evaluates the nominated essential uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on essential use nominations at their annual meeting.

EPA is responsible for allocating essential use allowances (EUAs) at the domestic level through rulemaking in accordance with provisions in the CAA. The CAA provides a specific exemption from the phase-out of class I ODSs at section 604(d)(2) that allows for the continued import and production of CFCs for use in medical devices. Today's action allocates EUAs for CFCs for use in metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary disease (COPD) for calendar year 2001. EPA is also allocating methyl chloroform for use in the Space Shuttle and the Titan Rocket for calendar year 2001 under the authority of the statutory phase-out at section 604(a). Today's action also amends the regulations at 40 CFR 82.12 to allow transfer of EUAs for CFCs among MDI companies who hold essential use allowances.

Overview of the Notice of Proposed Rulemaking

The Notice of Proposed Rulemaking (NPRM) proposing to allocate essential use allowances for calendar year 2001 was published on October 6, 2000 (65 FR 59783). In the NPRM, EPA proposed to allocate CFCs for use in metered dose inhalers (MDIs) and methyl chloroform for use in the Space Shuttle and Titan Rocket. EPA proposed to allocate a total of 3098.67 metric tons of CFCs, which is the quantity that the Food and Drug Administration (FDA), in consultation with EPA, determined to be ''necessary'' for use in MDIs. The total amount of essential use authorizations for MDIs granted to the U.S. by the Parties to the Montreal Protocol for 2001 is 3,101 metric tons. We explained in the NPRM that it would not be possible to allocate CFCs in an amount higher than allocated to the U.S. by the Parties to the Protocol. EPA also proposed changes to the regulations at 40 CFR 82.12 that would allow transfer of EUAs for CFCs among essential use holders. We also proposed to allocate 60.1 metric tons of methyl chloroform (MCF) for use in the Space Shuttle and Titan Rockets.

EPA received a total of eight comments on the NPRM. Six comments were from individual companies who produce MDIs,[2] one was from a consortium group that represents MDI manufacturers,[3] and one was from Friends of the Earth. Three commenters expressed support for the provision to allow transfer of EUAs for CFCs between allowance holders. One commenter requested additional EUAs to meet their projected needs for MDI production in 2001 without utilizing their strategic reserves. Two companies requested that their EUAs be reapportioned between them, but in the aggregate did not request an increase in EUAs. One commenter stated that EPA and FDA had improperly interpreted the

[1] ''Consumption'' is defined as the amount of a substance produced in the United States, plus the amount imported, minus the amount exported to Parties to the Montreal Protocol (*see* section 601(6) of the Clean Air Act). Stockpiles of class I ODSs produced prior to the 1996 phase-out can continue to be used for purposes not expressly banned at 40 CFR part 82, subpart C—Ban on Nonessential Products Containing Class I Substances and Ban on Nonessential Products Containing or Manufactured with Class II Substances.

[2] Pharmaceutical companies who commented were the following: Aventis Pharmaceuticals, 3M Pharmaceuticals, Boehringer Ingelheim Pharmaceuticals Inc., Schering Corporation, Sidmak Laboratories Inc., Glaxo Wellcome.

[3] The International Pharmaceutical Aerosol Consortium represents the following companies: AstraZeneca, Boehringer Ingelheim, Celltech-Medeva, Cheisi Farmaceutici, Glaxo Wellcome, and Norton Healthcare.

exemption for medical devices in the Act, and should not allocate CFCs for MDI products where an alternative propellant is available. Another commenter stated that the Act does not require EPA to transfer to FDA the responsibility to determine the amount of the allocation for CFCs, and that the FDA decision making process for determining the amount of CFCs necessary should be more transparent. EPA will summarize and address all comments in the body of this preamble. There were no comments on the proposed allocation of MCF for use in the Space Shuttle and Titan Rockets.

How Do the Parties to the Montreal Protocol Define an ''Essential Use''?

Decision IV/25 of the Parties to the Montreal Protocol set forth the criteria for determining whether a particular use of class I ODS is ''essential'' and would thus be eligible to receive EUAs for controlled substances. This decision states the following:

''(1) that a use of a controlled substance should qualify as 'essential' only if:

(i) It is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

(ii) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

(2) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(i) all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and

(ii) the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances.''

What Was the International Procedure for Approving Essential Use Exemptions for the Year 2001?

The international process for nominating and approving essential use allowances for the year 2001 occurred in the same way as in prior years. The companies in Table I submitted applications either on their own or as a part of the International Pharmaceutical Aerosol Consortium (IPAC), requesting class I ODSs for essential uses in response to the August 10, 1998 **Federal Register** document (63 FR 42629). Their applications requested exemptions for the production and import of specific quantities of certain class I controlled substances after the phase-out, and provided information in accordance with the criteria in Decision IV/25 of the Protocol and the procedures outlined in the ''1997 Handbook on Essential Use Nominations.'' EPA reviewed the applications and nominated these uses to the Protocol Secretariat for consideration by the Technical and Economic Assessment Panel (TEAP) and its Technical Options Committees. MDI producers requested a total of 3,101 metric tons of CFCs for use in 2001. The Parties to the Montreal Protocol approved this amount as essential for the U.S. for 2001 at the Eleventh Meeting in 1999 (Decision XI/14). On September 15, 1999, EPA issued another notice requesting supplemental applications for essential use allowances for the year 2001 and beyond (64 FR 50083). No company requested a supplemental amount of CFCs for the year 2001 at that time.

How Does the Clean Air Act Authorize Essential Use Allowances for MDIs?

Section 604(d)(2) of the CAA provides a standing exemption to the phase-out of class I ODSs for the production and importation of CFCs for use in medical devices which reads:

> ''Notwithstanding the termination of production required by subsection (b), the Administrator, after notice and opportunity for public comment, shall, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of class I substances solely for use in medical devices if such authorization is determined by the Commissioner, in consultation with the Administrator, to be necessary for use in medical devices.''

Section 601(8) of the Clean Air Act defines the term ''medical device'' and states the following:

> [A]ny device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system—
>
> (A) if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner [of FDA]; and
>
> (B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner [of FDA] in consultation with the Administrator [of EPA].

As discussed in the NPRM, EPA is relying on FDA regulations at 21 CFR 2.125 to provide determinations of whether a ''safe and effective alternative'' is available for any particular CFC MDI. It should be noted that FDA approval of a non-CFC product is a determination that the product is safe and effective, but it is not a determination that the product is a ''safe and effective alternative'' for any other CFC MDI product under the Act. FDA states in their notice of proposed rulemaking on essential use determinations that ''a non-CFC product simply having the same active moiety as a CFC product is only one factor to be considered. Other factors, such as whether the non-CFC product has the same route of administration, the same indication, and can be used with approximately the same level of convenience, are important considerations. Additionally, FDA must consider whether patients who medically need the CFC product are adequately served by the non-CFC product.'' (September 1, 1999, 64 FR 47735). While FDA has approved two non-CFC MDIs as of December 1, 2000, FDA has yet not identified any ''safe and effective alternative'' to any CFC MDI as specified by section 601(8)(A). Thus, part (A) of the definition of medical device has been met, and is consistent with today's rulemaking.

With respect to section 601(8)(B), EPA is relying on current FDA regulations (21 CFR 2.125) listing medical devices that FDA has found to be essential. The companies for which EPA is granting essential use allowances produce CFC MDIs covered by this regulation. Thus, the products for which EPA is granting essential use allowances are ''determined to be essential'' by FDA.

One commenter stated that under section 601(8)(A), EPA must determine that no safe and effective alternative propellant exists for any MDI to meet the definition of ''medical device.'' EPA believes that the phrase ''safe and effective alternative'' at section 608(1)(A) does not refer an alternative propellant, but refers to a ''safe and effective alternative'' to a CFC MDI. This is because FDA only approves MDIs under a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) as a whole unit and not by approving each of its components. Therefore, it is impossible for FDA to approve an alternative to the class I or class II substance (*i.e.* the propellant) alone, and it is reasonable to conclude that the phrase ''safe and effective alternative'' refers to an adequate replacement for the CFC MDI product.

This commenter also quoted a passage from the legislative history of the 1990 Amendments which states that ''unless a safe substitute exists or until a

substitute is developed and approved by FDA, a drug delivery system may be found by the Commissioner and the Administrator to be essential'' (S. Rep No. 228, 101st Cong., 1st Sess. 1989, 1990). The commenter believes that this passage supports their belief that once a drug containing a safe and effective alternative propellant has been approved by FDA, FDA has no authority to continue to designate analogous CFC-containing products as ''essential''. In response, we note that the term ''drug delivery system'' indicates that Congress envisioned that FDA would need to approve an entire non-CFC drug delivery system, and not just the alternative propellant. Further, the use of the term ''substitute'' indicates that Congress was looking to FDA to determine whether a non-CFC MDI is a safe and effective replacement for a particular CFC MDI (*i.e.* a ''safe and effective alternative''). While this report refers to Senate language which is somewhat different from what appears in the 1990 Amendments, the Senate's intent, revealed by this passage is consistent with EPA and FDA's interpretation of the Act.

The commenter also states that the safety and efficacy of alternatives to CFCs is determined by EPA under section 612 of the CAA, and that EPA had stated that it would rely upon FDA's approval of medical products containing alternative propellants under the Food Drug and Cosmetic Act (FDCA) for a determination that there are no human health effects from the use of the alternative propellant. Thus, the commenter believes that when FDA approves a non-CFC MDI as safe and effective under the FDCA, EPA must conclude that the non-CFC propellant in that product is safe and effective for the purposes of the CAA. In fact, EPA has already reviewed the health risks associated with alternative aerosol propellants for use in non-CFC MDIs under section 612 of the Act. Nevertheless, EPA disagrees with the assertion that a determination that an alternative propellant to an ODS is acceptable under section 612 of the Act has any bearing on the determination of whether a non-CFC MDI is a ''safe and effective alternative'' to a CFC MDI as required by section 601(8)(A).

The commenter states that when a non-CFC MDI is approved under the FDCA, only CFC-based products containing the same active moiety, and the same labeled indications would no longer qualify as ''medical devices'' under the Act, and that in instances where the labeled indications of a non-CFC drug do not fully duplicate those of a CFC product, EPA may only authorize production of limited quantities of CFCs that the EUA applicant demonstrates are necessary to serve patients not covered by the non-CFC drug product's indications. EPA believes that the commenter is wrong to assert that because a safe and effective non-CFC MDI is available, EPA should deem CFC MDIs with the same active moiety to be non-essential for the purposes of the CAA. As stated earlier, FDA approval of a non-CFC product is a determination that the product is safe and effective, but it is not a determination that the product is a safe and effective alternative for any other product under the Act. Because FDA has yet not identified any ''safe and effective alternative'' for any CFC MDI, today's allocation of CFCs for essential uses remains consistent with section 601(8)(A).

The commenter's suggestion that EPA make medical decisions regarding whether a non-CFC MDI is an adequate alternative to a CFC MDI produces a result that would put asthma patient health at risk. FDA is the appropriate agency with expertise to make independent medical decisions that directly affect patients. The determination that a CFC MDI is no longer ''essential'' is not, as the commenter suggests, one where EPA could merely look at the active moiety of the product, read the non-CFC product indication, compare it to the CFC MDI product indication, and determine any CFC MDIs to be non-essential. FDA states in their notice of proposed rulemaking on essential use determinations that ''a non-CFC product simply having the same active moiety as a CFC product is only one factor to be considered. Other factors, such as whether the non-CFC product has the same route of administration, the same indication, and can be used with approximately the same level of convenience, are important considerations. Additionally, FDA must consider whether patients who medically need the CFC product are adequately served by the non-CFC product.'' (September 1, 1999, 64 FR 47735). Most of these factors are not addressed on the indication label of an MDI. Thus the indication label alone cannot be used as the basis for determining whether a non-CFC product is an adequate alternative for any CFC MDI.

We believe that the overall purpose of the language in the Act regarding medical devices is to ensure that EPA's mission of environmental protection does not conflict with FDA's mission of protecting the patient health. Consistent with this purpose, we believe that in drafting the definition, Congress was focusing on the availability of adequate alternative medical treatment for patients who rely on CFC MDIs. EPA is not the appropriate agency to decide whether such alternative medical treatment is available. We do not believe that Congress intended EPA to make decisions involving medical judgement and expertise. On such questions, we have and will continue to defer to FDA.

The commenter states that FDA must approve and determine that the CFC-containing MDI is essential after notice and an opportunity for public comment, and asserts that once a drug containing a safe and effective alternative propellant has been approved by FDA, FDA has no authority to continue to designate analogous CFC-containing products as ''essential''. Further, the commenter states that EPA may not wait for FDA to remove that product from its list of essential uses before finding that it no longer qualifies as a ''medical device'' under the Act. Again, EPA believes that this interpretation of the Act is flawed. This is because section 601(8)(B) refers to approval of an alternative as occurring after ''notice and opportunity for comment.'' Because FDA does not approve alternative propellants, and because approval of a specific MDI drug product through the New Drug Application or Abbreviated New Drug Application system under the FDCA involves unilateral action by FDA without notice-and-comment rulemaking or consultation with EPA, it is reasonable to conclude that section 601(8)(B) refers to FDA's approval of an essential use listing in 21 CFR 2.125 which does involve notice and comment rulemaking. Thus, EPA believes that by allocating CFCs for products covered by the list of ''essential'' products at 21 CFR 2.125, we have fulfilled the requirements of section 601(8)(B).

Finally, the commenter states that FDA cannot use the categorical exemptions at 21 CFR 2.125 created more than twenty years ago to establish the essentiality of particular CFC MDI under the statute today, and that by doing so EPA and FDA are not relying on standards adopted under the Act in 1990. EPA believes that our explanation of this issue in the interim final rule allocating essential use allowances for calendar year 2000 still stands (see 65 FR 716, January 6, 2000).

While we are aware that FDA is currently engaged in rulemaking to revise its essential use regulations, we are relying on FDA's current essential use list at 21 CFR 2.125 for purposes of today's action. The statute does not specify a particular time at which FDA must make such a determination or

invalidate determinations made prior to the date of the 1990 CAA Amendments. Additionally, the 1990 CAA Amendments use language consistent with FDA's regulations at 21 CFR 2.125. We presume that Congress was aware of FDA's regulations when it passed the 1990 Amendments to the CAA. Therefore, we believe that the current essential use list remains valid. If FDA revises its regulations, we will take the revised list into account in future allocation decisions. EPA further notes that both EPA and FDA are implementing the more stringent provisions of the Montreal Protocol as specified by section 614(b) of the Act [4] by following the essentiality determinations of the Parties to the Montreal Protocol in allocating new CFCs.

How Does the CAA Authorize the Exemption for Methyl Chloroform?

With today's action, EPA is allocating methyl chloroform (MCF) for use in the Space Shuttle and Titan Rockets under the statutory phase-out schedule at section 604(a). This section provides that MCF may be produced at up to 20 percent of the amount produced in 1989 (the baseline year as specified at section 601(2)(B) of the Act). EPA is allocating a total of 60.1 metric tons of MCF, an amount well below 20% of the baseline year production of 315,169 metric tons for MCF (defined at 40 CFR 82.6).

Section 604(a) of the Act requires the complete phase-out of production of MCF after 2001. As a result, it is likely that EPA will be required to rely solely upon the exemption under section 604(d)(1), that may already be applicable, for the year 2002 and beyond. This exemption reads as follows:

(1) Essential Uses of Methyl Chloroform.—Notwithstanding the termination of production required by subsection (b), during the period beginning on January 1, 2002, and ending on January 1, 2005, the Administrator, after notice and opportunity for public comment, may, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of methyl chloroform solely for use in essential applications (such as nondestructive testing for metal fatigue and corrosion of existing airplane engines and airplane part susceptible to metal fatigue) for which no safe and effective substitute is available.

EPA understands that research on alternatives is progressing well, and that in the year 2002 there may be no need for an essential use exemption for MCF. Nevertheless, EPA believes that section 604(d)(1) may allow for the continued limited use of methyl chloroform for Space Shuttle and Titan Rocket through 2004 under the essential use exemption as long as no substitute is available.

II. Allocation Process for CFCs for Use in Medical Devices for the Year 2001

As explained earlier, section 604(d)(2) of the Act provides that EPA shall authorize production and import of limited quantities of class I substances for use in medical devices if FDA, in consultation with EPA, determines such authorization to be ''necessary.'' Thus, EPA in order to implement the exemption for medical devices must receive a formal determination on the amount of CFCs necessary for use in MDIs from FDA. FDA sent EPA a letter dated September 6, 2000 that provided their determination on the amount of CFCs necessary, and explained the bases for that determination.

One commenter stated that the CAA does not delegate to FDA the authority to dictate the nomination quantity and allocation of class I substances for medical devices. Rather, according to the commenter, the CAA requires that EPA shall consult with FDA only as to whether the authorization of class I substances for medical devices is necessary, which requires a yes/no determination only. Thus, EPA should not transfer to the FDA the responsibility to determine the quantity of essential use allowances allocated to companies.

EPA has addressed the comment that is raised here in the preamble to essential use allocation for calendar year 2000 (65 FR 40524, 40530–40537). We believe that the same interpretation and explanation provided in the previous rulemaking is applicable here. Section 604(d)(2) states the following: ''The Administrator, after notice and opportunity for public comment, shall, to the extent such action is consistent with the Montreal Protocol authorize the production of limited quantities of class I substances solely for use in medical devices if such authorization is determined by the Commissioner [of FDA], in consultation with the Administrator [of EPA], to be necessary for use in medical devices.'' (emphasis added) EPA believes that it is clear that the authorization in question is not for an indefinite amount but for ''limited quantities.'' It is equally clear that the subject of the Commissioner's determination of necessity is ''such authorization.'' Thus, if the latter part of the text quoted above were written in the active voice, it would say: ''if the Commissioner, in consultation with the Administrator, determines such authorization to be necessary for use in medical devices.'' We note that the expression ''such authorization'' refers back to the phrase ''authorize the production of limited quantities of class I substances solely for use in medical devices.'' Thus, the Commissioner of FDA must consider not only whether any production is necessary, but what quantity of production is necessary for MDIs.

Further, although EPA does have some data on CFC usage (which is shared with FDA), only FDA personnel are privy to confidential business information regarding annual sales and distribution of MDIs. This provides FDA with more complete knowledge of the MDI market than EPA. Because of FDA's access to additional information, and their medical expertise which is integral to making decisions that serve to protect the public health, EPA believes it is consistent with Congressional intent to consult with FDA in making decisions regarding the amount of CFCs necessary for the production of MDIs.

The commenter's second point was that EPA should ensure that the rationale for adjustments made to allocations and the bases for FDA recommendations are open and available to the public for review and comment. EPA agrees that the allocation process should be as transparent as possible while accounting for the confidential nature of the data employed to make the determination on the amount of CFCs necessary. To this end, EPA and FDA planned a process described in the NPRM that we felt would allow this determination on the amount of CFCs necessary to occur as openly as possible. EPA sent letters pursuant to section 114 of the Act to each essential use applicant requesting specific information such as the number of units of each product produced in previous years, the number of units produced in the first quarter 2000, the gross target fill weight per unit, the total amount of CFCs to be contained in the product in 2001, the number of units of each product anticipated to be produced in 2001, the additional amount of CFCs necessary for production, and the total amount of CFCs requested for each product in 2001. FDA, in consultation with EPA, based the determination of necessary amounts and the allocation on this information. Thus, each company knows what information it has submitted as the basis for its own allocation while protecting against disclosure of confidential business information to competitors. Finally, we placed all non-confidential materials in

[4] Section 614(b) states that ''* * * in the case of conflict between [the Act] and any provisions of the Montreal Protocol, the more stringent provision shall govern.''

the docket, including the FDA letter of September 6, 2000 that provided EPA with their recommendation on the amount of CFCs necessary for MDIs for the year 2001.

III. Allocation of Essential Use Allowances for Calendar Year 2001

EPA is allocating essential use allowances for calendar year 2001 to entities listed in Table I for exempted production or import of the specific quantity of class I controlled substances solely for the specified essential use. The allocation of CFCs for use in MDIs reflects the determination on the amount of CFCs ''necessary'' as specified under section 604(d)(2) of the Act taking into account two companies requests for reapportioning EUAs among them.

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2001

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
Medeva, Armstrong Pharmaceuticals Inc.	CFC–11 or CFC–12 or CFC–114	189.00
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	338.36
Glaxo Wellcome Inc.	CFC–11 or CFC–12 or CFC–114	858.10
Aventis Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	190.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	304.51
Sidmak Laboratories/Medisol Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	192.20
Schering Corporation	CFC–11 or CFC–12 or CFC–114	1025.20
Sciarra Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	1.30
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

Was the Allocation Listed in This Proposed Rule Changed in the Final Rule?

The total amount of CFCs allocated for use in MDIs is the same as in the proposed rule. However, the amount of EUAs allocated to two MDI companies was reapportioned between them at their request. One commenter is the New Drug Application (NDA) holder, and the other is a contract filler for that NDA holder. The NDA holder stated that they had reassessed the amount of MDIs the contract filler would produce for them in 2001. The NDA holder requested that a certain amount of EUAs allocated to their contract filler and earmarked for the production of the NDA holder's products be re-apportioned back to the NDA holder. The contract filler provided comments that supported the transfer of EUAs from them to the NDA holder (this contract filler is also an essential use allowance holder with its own allocation for production of its own MDIs). EPA believes that in this case, it is not necessary for FDA to approve this adjustment to the essential use allocations because the total amount of EUAs allocated for use in the NDA holder's MDI products (*i.e.* the MDIs to be produced by the NDA holder themselves plus the MDI to be produced by contract filler) remains unchanged. Further, EPA is implementing provisions to allow transfer of EUAs between MDI companies. This provision, finalized in today's action, would allow this transfer to occur even in the absence of EPA re-apportioning the EUAs among these two companies.

One company requested additional volumes of CFCs beyond the amount allocated to them in the NPRM. This company stated that it had anticipated an earlier timing for launch of certain new products, and that their current supplier of pharmaceutical-grade CFCs may shut down production in the next few years. For these reasons, they requested additional EUAs for calendar year 2001 to continue MDI production without utilizing their strategic reserves.

EPA and FDA have concluded that the year 2001 essential use allocations already reflect the contingencies raised by the commenter and are protective of public health. These allocations are calculated to insure that the full range of medical needs is met throughout the entire patient population. It should be noted that this company, as well as all essential use holders, now have the opportunity to obtain additional EUAs through trading, and also had the opportunity to request additional CFCs for the year 2002 in response to the notice requesting essential applications for the years 2002 and 2003 published November 1, 2000 (65 FR 65311).

Were There Other Comments Regarding the Allocation of CFCs for Use in MDIs?

One commenter who is a generic producer of MDIs stated that they were pleased with their proposed allocation. However, they commented that had they not been allocated EUAs, or had received an extremely low allocation, opportunities due to unexpected shifts in the market would fall to foreign manufacturers of MDIs who, the commenter asserts, can export CFC MDIs to the U.S. and are not subject to the same allocation requirements as U.S. MDI producers. EPA notes that companies who produce MDIs in other countries are also subject to the terms of the Montreal Protocol and must receive an allocation for CFCs to produce ''essential'' MDIs [5]. The major production of MDIs abroad is in Europe where each company's CFC requirements are also extensively reviewed before allocation.

What Was EPA's Method for Allocating Methyl Chloroform (MCF) for Use in Solid Rocket Motors?

With this action, EPA is allocating 60.1 metric tons of MCF for use in solid rocket motors, the same amount allocated in the years 1999 and 2000. EPA proposed to allocate MCF in an amount lower than would be consistent with Decision X/6 taken at the Tenth meeting of the Parties to the Protocol because we believed, based on knowledge of past MCF use, that allocating a larger amount would be unnecessary. EPA did not receive any comments on this issue, and is allocating 60.1 metric tons MCF as proposed in the NPRM.

[5] EPA believes that all countries that produce MDIs are parties to the Montreal Protocol.

When Is This Rule Effective?

This final rule is effective on January 8, 2001. Section 553(d) of the APA generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. However, APA section 553(d) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action grants an exemption to the phase-out of production and consumption of CFCs, EPA is making this action effective immediately to ensure the availability of CFCs for medical devices during calendar year 2001.

Why is EPA Allocating CFC–11, CFC–12, and CFC–114 in the Aggregate To Each Company?

As discussed in the proposal, EPA is allocating essential use allowances for CFC–11, CFC–12, and CFC–114 in the aggregate in accordance with Decision X/6 of the Parties to the Montreal Protocol which states that ''the quantities approved under paragraph 2 above and all future approvals are for total CFC volumes with flexibility between CFCs within each group.'' Allocating CFCs for MDI in the aggregate instead of on a compound-by-compound basis provides MDI producers with flexibility in obtaining CFCs without causing additional damage to the stratospheric ozone layer since CFC–11, CFC–12 and CFC–114 all have the same ozone depleting potential of 1.0.

Timing of This and Future Essential Use Allocation Rules

One commenter noted that even though EPA sent letters to MDI companies in May 2000 requesting data needed to determine 2001 EUAs, the proposed allocation was not published until October. This commenter requested that EPA make every effort to issue a proposed rule allocating EUAs for 2002 in September of 2001, and states that as pharmaceutical-grade CFC production becomes increasingly tenuous, CFC suppliers are requiring advanced notice of MDI companies' CFC production needs. Further, MDI companies are unable to provide suppliers with this information until final EUA allocations are issued. Earlier rulemakings would help to ensure that MDI manufacturers are able to place CFC production orders, arrange for shipping, and make other administrative arrangements in a timely manner. EPA will make every effort to issue the notice of proposed rulemaking allocating essential use allowances for 2002 by September of 2001.

Another commenter requested that EPA issue the final CFC allocations for 2001 as soon as possible so that necessary CFCs may be ordered and delivered from the supplier in Europe in time to meet MDI production needs in 2001. EPA has expedited this final rule and believes that companies should have sufficient time to place their orders for CFCs for the coming year.

What Reporting Requirements Must I Adhere To When Using My Essential Use Allocation?

Any person obtaining class I controlled substances after the phase-out under the essential use exemptions in today's action is subject to all the restrictions and requirements in other sections of 40 CFR part 82, subpart A. Holders of essential use allowances or persons obtaining class I controlled substances under the essential use exemptions must comply with the recordkeeping and reporting requirements in 40 CFR 82.13. Instructions and forms for reporting are found in the Guidance Document for the Stratospheric Ozone Protection Program after January 1, 1996. This document can be obtained by contacting the Stratospheric Ozone Protection Hotline at (800) 296–1996 between 10:00 am and 4:00 pm Eastern Standard Time.

Under 40 CFR 82.3 and 82.4 (63 FR 41626, August 4, 1998), entities receiving essential use allowances must be the importer of record for quantities of CFCs brought into the United States. This requires that the essential use allowance holder be listed as the importer of record on Customs Form 7501. As a result, the essential use allowance holder who imports quantities of class I controlled substances is responsible for submitting both an Importer Quarterly Report and an Essential Use Holder Quarterly Report.

IV. Transfer of EUAs for CFCs Among Essential Use Allowance Holders

With this action EPA is adding essential use allowances to the list of allowances that can be transferred under 40 CFR 82.12. This change will enable companies to transfer EUAs for CFCs to other essential use holders for the production of MDIs. EPA believes that allowing EUAs to be transferred among essential use allowance holders will allow MDI companies to obtain CFCs beyond their allocation without increasing the total amount of ODSs allocated. EPA received three comments in support of the provision to allow transfer of EUAs among essential use holders. These commenters stated that this provision provides a responsible mechanism for addressing the inherent problem in attempting to predict the needs for MDI manufacturers.

One commenter requested a clarification of the proposed regulations regarding the use of a contract filler. The commenter took issue with the fact that EPA would have to approve the use of a contract filler. The commenter believes it should be at the company's discretion as to whether it produces the product in-house or through the use of a contract filler. The new regulations provide a mechanism for transfer of EUAs from an NDA holder to a contract filler (provided they already have EUAs). However, EPA must continue to exercise strict control over the amount of CFCs produced and or imported to ensure U.S. compliance with the Decisions of the Parties to the Protocol. Thus, EPA believes that it is necessary to approve the transfer of EUAs between an NDA holder and a contract filler. It should be noted that EPA is not approving or disapproving the use of a contract filler per se, but merely ensuring that the ''transferor'' has sufficient allowances to cover the transaction.

Under the New Regulations Can I Transfer EUAs for CFCs To Anyone I Want?

No; EUAs for CFCs are only transferable among those companies that have applied for and received EUAs for the year 2001. In addition, companies must certify in writing to EPA that the EUAs will only be used in the production of essential medical devices as defined in the FDCA at 21 CFR 2.125 and considered essential by the Parties to the Protocol.

Can EUAs for CFCs Be Transferred From Year to Year?

No; EUAs are not transferable from year to year. Any EUAs for CFCs not expended in 2001 will expire at the end of 2001.

Is There a Cost for Transferring EUAs?

Yes; the CAA at section 607(a) states that rules governing transfer of allowances for the production of class I and class II substances ''* * * shall insure that the transactions under the authority of this section will result in greater total reductions in the production in each year of class I and class II substances than would occur in that year in the absence of such transactions.'' In compliance with this section, current regulations at 40 CFR 82.12 governing transfers of production and consumption allowances require one percent of the traded amount to be deducted from the transferor's

unexpended allowances. EPA proposed to amend the regulations so that in the case of EUA transfers, one tenth of one percent of the amount traded would be deducted from the transferor's account. As stated in the preamble to the proposed rule, EPA believes that given the relatively small amount of EUAs available for use in MDIs, and that providing sufficient EUAs for MDIs is critically important for protecting public health, deducting one percent of the amount of EUAs to be traded would be too high a penalty and may create a barrier against transferring EUAs freely. Reducing the amount deducted from the transferor's account overcomes this potential barrier. EPA received no adverse comments on this issue, and is amending the regulation as described above.

How Can I Transfer EUAs From My Company to Another?

In order to complete a transfer of EUAs for CFCs from one essential use allowance holder to another, the transferor would have to submit to the Administrator a letter with the information requested in 40 CFR 82.12(a)(1). Under the regulations at 40 CFR 82.12, the transferor must submit to the Administrator a transfer claim with the following information:

1. The identities and addresses of the transferor and transferee.
2. The names and telephone numbers of contact persons for both the transferor and transferee.
3. The type of allowances being transferred, which in this case would always be essential use allowances.
4. The group of controlled substances being transferred, which would always be Group I.
5. The amount of allowances being transferred in kilograms.
6. The calendar year for which the allowances are being transferred (*e.g.* calendar year 2001).
7. The amount of unexpended essential use allowances for the current calendar year.
8. The amount of the 0.1% offset applied to the unweighted amount traded that will be deducted from the transferor's allowance balance.

A sample form that outlines the necessary information that a transferor must submit to EPA will be available through the Stratospheric Ozone Hotline at 1–800–296–1996.

As specified in 40 CFR 82.12, EPA will determine, based on records maintained by the EPA ODS tracking system, whether the transferor possesses as of the date of the transfer claim, unexpended allowances sufficient to cover the transfer claim (*i.e.,* the amount to be transferred plus one tenth of one percent of that amount). Within three working days of receiving a complete transfer claim, EPA will notify the transferor and transferee if the transferor has sufficient unexpended allowances to confer the transfer claim, and will issue a notice indicating that EPA does not object to the transfer. EPA will then reduce the transferor's balance of essential use allowances by the amount to be transferred plus one tenth of one percent of that amount. When EPA issues a no objection notice, the transferor and the transferee may proceed with the transfer.

If EPA's records show that the transferor has insufficient unexpended allowances to cover the transfer claim, or that the transferor has failed to respond to one or more Agency requests to supply information needed to make a determination, EPA will issue a notice disallowing the transfer. Within 10 working days after receipt of notifications, either party may file a notice of appeal, with supporting reasons, to EPA, in which case EPA may either affirm or vacate the disallowance. If no appeal is taken by the tenth working day after notification, the disallowance shall be final on that day. (The transferor and transferee will be held liable in accordance with section 113 of the Act for any violations that occur as a result of an improper transfer.) In the event that EPA does not respond to a transfer claim within three working days of receipt of the completed claim, the transferor and transferee may proceed with the transfer and EPA will reduce the transferor's balance accordingly.

V. Administrative Requirements

A. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 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 by State, local, and tribal governments, in the aggregate, or by 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. Section 204 of the UMRA requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

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 Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, or tribal governments or the private sector. Because this rule imposes no enforceable duty on any State, local or tribal government it is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments; therefore, EPA is not required to develop a plan with regard to small governments under section 203. Finally, because this rule does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials under section 204.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is Significant and therefore subject to OMB review and the requirements of the Executive Order. The Order defines Significant regulatory action as one that is likely to result in a rule that may:

(1) 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;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined by OMB and EPA that this action is not a Significant regulatory action under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order.

C. Paperwork Reduction Act

This action does not impose any new information collection burden as defined by the Paperwork Reduction Act (PRA). The Office of Management and Budget's draft guidance on PRA states that a rule is exempt from OMB review if it ''explicitly applies to nine or fewer persons''. Since the reporting requirements in this rule are not of general applicability, and apply only to the eight entities receiving EUAs for CFCs, and only if a company decides to transfer EUAs to another essential use holder, we believe that this rule is exempt from the requirement of submitting an Information Collection Request and undergoing OMB review.

However, OMB has previously approved the information collection requirements that are contained in the existing regulations at 40 CFR 82.12 that set forth the process for inter-company transfers of consumption allowances under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0170 (EPA ICR No.1432.17). Copies of the ICR document(s) may be obtained from Sandy Farmer, by mail at the Office of Environmental Information, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at farmer.sandy@epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the internet at http://www.epa.gov/icr. Include the ICR and/or OMB number in any correspondence.

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.

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.

D. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility

After considering the economic impacts of today's proposed rule on small entities, EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this rule. EPA has also determined that this action will not have a significant economic impact on a substantial number of small entities. This rule does not have a significant impact on a substantial number of small entities. There are only ten entities that are affected by this rulemaking (see table I above). This rule does not have an adverse economic impact on any entity because it grants exceptions to a pre-existing ban.

F. Applicability of Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (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 and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or 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. EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it implements the phase-out schedule and exemptions established by Congress in title VI of the Clean Air Act.

G. National Technology Transfer and Advancement Act

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) directs EPA to use voluntary consensus standards in this 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 standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This final rule does not involve technical standards. Therefore, EPA did not

consider the use of any voluntary consensus standards.

H. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 432255, 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'' 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.'' Under 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 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.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner. This rule will not 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, as specified in Executive Order 13132. This rule will affect only the ability of private entities and the national government to request production of controlled ozone-depleting substances. Thus, the requirements of section 6 of the Executive Order to not apply to this rule.

VI. Judicial Review

Under section 307(b)(1) of the Act, EPA finds that these regulations are of national applicability. Accordingly, judicial review of the action is available only by the filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit within sixty days of publication of the action in the **Federal Register**. Under section 307(b)(2), the requirements of this rule may not be challenged later in the judicial proceedings brought to enforce those requirements.

VII. Submittal to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Therefore, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective January 8, 2001.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Exports, Imports, Reporting and recordkeeping requirements.

Dated: December 28, 2000.

Carol M. Browner,

Administrator.

40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.4 is amended by revising the table in paragraph (t)(2) to read as follows:

§ 82.4 Prohibitions.

* * * * *

(t) * * *

(2) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2001

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
Medeva Americas, Inc.	CFC–11 or CFC–12 or CFC–114	189.00
Boehringer Ingelheim	CFC–11 or CFC–12 or CFC–114	338.36
Glaxo Wellcome	CFC–11 or CFC–12 or CFC–114	858.10
Aventis	CFC–11 or CFC–12 or CFC–114	190.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	304.51
Sidmak Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	192.20
Schering Corporation	CFC–11 or CFC–12 or CFC–114	1025.20
Sciarra Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	1.3
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

* * * * *

3. Section 82.12 is amended by revising paragraphs (a)(1) introductory text, (a)(1)(i)(H), (a)(1)(ii) introductory text, (a)(1)(ii)(A), and (a)(1)(iii) to read as follows:

§ 82.12 Transfers.

(a) * * *

(1) Until January 1, 1996, for all class I controlled substances, except for Group VI, and until January 1, 2001, for Group VI, any person (''transferor'') may transfer to any other person (''transferee'') any amount of the transferor's consumption allowances or production allowances, and effective January 1, 1995, for all class I controlled substances any person (''transferor'') may transfer to any other person (''transferee'') any amount of the transferor's Article 5 allowances, and after January 1, 2001 any essential use allowance holder (''transferor'') may transfer essential use allowances for CFCs to any other essential use allowance holder for CFCs (''transferee'') solely for the production of essential products (defined at 21 CFR 2.125) as follows:

(i) * * *

(H) The amount of the one percent offset applied to the unweighted amount traded that will be deducted from the transferor's production or consumption allowance balance (except for trades from transformers and destroyers to producers or importers for the purpose of allowance reimbursement). In the case of transferring essential use allowances, the amount of one tenth of one percent of the amount traded will be deducted from the transferor's allowance balance.

(ii) The Administrator will determine whether the records maintained by EPA, taking into account any previous transfers and any production, allowable imports and exports of controlled substances reported by the transferor, indicate that the transferor possesses, as of the date the transfer claim is processed, unexpended allowances sufficient to cover the transfer claim (*i.e.,* the amount to be transferred plus, in the case of transferors of essential use allowances, one tenth of one percent of the transferred amount, and in the case of transferors of production or consumption allowances, one percent of the transferred amount). Within three working days of receiving a complete transfer claim, the Administrator will take action to notify the transferor and transferee as follows:

(A) If EPA's records show that the transferor has sufficient unexpended allowances to cover the transfer claim, the Administrator will issue a notice indicating that EPA does not object to the transfer and will reduce the transferor's balance of unexpended allowances by the amount to be transferred plus, in the case of transfers of production or consumption allowances, one percent of that amount, or in the case of transfers of essential use allowances, one tenth of one percent of that amount. When EPA issues a no objection notice, the transferor and the transferee may proceed with the transfer. However, if EPA ultimately finds that the transferor did not have sufficient unexpended allowances to cover the claim, the transferor and transferee will be held liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

* * * * *

(iii) In the event that the Administrator does not respond to a transfer claim within the three working days specified in paragraph (a)(1)(ii) of this section, the transferor and transferee may proceed with the transfer. EPA will reduce the transferor's balance of unexpended allowances by the amount to be transferred plus, in the case of transfers of production or consumption allowances, one percent of that amount, and in the case of essential use allowances, one tenth of one percent of that amount. However if EPA ultimately finds that the transferor did not have sufficient unexpended allowances to cover the claim, the transferor and transferee will be held liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

* * * * *

[FR Doc. 01–463 Filed 1–5–01; 8:45 am]

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Federal Register

Monday,
January 8, 2001

Part VI

Department of Education

34 CFR Part 300

Assistance to States for the Education of Children With Disabilities; Final Rule

DEPARTMENT OF EDUCATION

34 CFR Part 300

RIN 1820–AB51

Assistance to States for the Education of Children With Disabilities

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations for the Assistance to States for the Education of Children with Disabilities program under Part B of the Individuals with Disabilities Education Act (IDEA; Part B)). This amendment is needed to implement the statutory provision that for any fiscal year in which the appropriation for section 611 ofthe IDEA exceeds $4.1 billion, a local educational agency (LEA) may treat as local funds up to 20 percent of the amount it receives that exceeds the amount it received during the prior fiscal year. The amendment is intended to ensure effective implementation of the 20 percent rule by clarifying which funds under Part B of IDEA can be included in the 20 percent calculation, and, as a result, to reduce the potential for audit exceptions.

DATES: These regulations are effective—February 9, 2001.

FOR FURTHER INFORMATION CONTACT: JoLeta Reynolds (202) 205–5507. If you use a telecommunication device for the deaf (TDD), you may call the TDD number at (202) 205–5465.

Individuals with disabilities may obtain this document in an alternate format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to Katie Mimcey, Director of the Alternate Formats Center. Telephone: (202) 205–8113.

SUPPLEMENTARY INFORMATION: On May 10, 2000, the Secretary published a notice of proposed rulemaking (NPRM) in the **Federal Register** (65 FR 30314) to amend the regulations governing the Assistance to States for the Education of Children with Disabilities program (34 CFR part 300). The NPRM proposed to implement a statutory provision regarding the permissive treatment of a portion of Part B funds by LEAs in certain fiscal years, as added by the IDEA Amendments of 1997 (see section 613(a)(2)(C) of the Act and § 300.233 of the regulations).

Under the new statutory provision, for any fiscal year (FY) for which the appropriation for section 611 of the IDEA exceeds $4.1 billion, an LEA may treat as local funds up to 20 percent of the amount it receives that exceeds the amount it received under Part B during the prior year. By treating certain Federal funds as local funds, and LEA will be able to meet the maintenance of effort requirement of § 300.231 even though it reduces the amount of other local or local and State funds, as the case may be, by an amount equal to the amount of Federal funds that may be treated as local funds. The fiscal year ending September 30, 1999 was the first year that the Part B appropriation exceeded $4.1 billion.

A key question the NPRM proposed to resolve was whether only LEA subgrant funds under section 611(g) of the Act or LEA subgrant funds and other Part B funding sources (*i.e.,* subgrants to LEAs for capacity-building and improvement under section 611(f), other funds the SEA may provide to LEAs under section 611(f) or preschool grant funds under section 619) would be affected by the 20 percent rule in section 613(a)(2)(C) of the Act (§ 300.233 of the regulations).

In the NPRM, we proposed that the 20 percent rule apply only to LEA subgrant funds under section 611(g) of the Act (§ 300.712 of the regulations), for the reasons described in the preamble to the NPRM. We believe that the position taken in the NPRM is the most appropriate and reasonable position to follow in implementing the 20 percent rule. Therefore, we have retained proposed § 300.233(a)(1), without change, in these final regulations.

There are only two significant differences between the NPRM and these final regulations:

- First, we have amended proposed § 300.233(a)(3) (which provided that if funds are being withheld from an LEA, those funds would not be included in the 20 percent calculation) to clarify that if funds that have been withheld are subsequently released to the LEA, the LEA may apply the 20 percent rule to those funds.
- Second, we have added (in a new Appendix C to the regulations for Part 300) information to assist LEAs in implementing the 20 percent rule, including a full, substantive description of the provision (with examples) that is similar to the information contained in the Background section of the preamble to the NPRM.

Analysis of Comments and Changes

In response to the Secretary's invitation in the NPRM, six parties submitted comments on the proposed regulations. An analysis of the comments and of the changes in the regulations since publication of the NPRM follows. In the analysis, we address substantive comments, but we do not address comments that are not directly relevant to these regulations.

Comment: The comments generally acknowledged the need for having the proposed regulation, but were varied in their recommendations for change. With respect to which funds under section 611 of the Act apply in determining the amount of money that will be treated as local funds, one commenter agreed with the position in the NPRM (*i.e.,* that the funds should be limited to LEA subgrants under section 611(g) (§ 300.712 of the regulations)). Two commenters recommended that the provision be expanded to also include funds for local capacity-building and improvement under section 611(f) of the Act (§ 300.622 of the regulations). Another commenter noted that States routinely flow through additional Part B (section 611) funds beyond the required LEA subgrants under section 611(g), and recommended that the regulations clarify that the 20 percent rule applies to all section 611 funds LEAs receive, including funds that are not retained by States for administrative purposes and other State-level activities specified under section 611(f).

Discussion: We believe that the position taken in the NPRM—that the money that may be treated by LEAs as local funds under the section 611 appropriation should be limited to statutory subgrant funds under section 611(g)—is the most appropriate and reasonable position to follow in implementing section 613(a)(2)(C) of the Act (§ 300.233 of the regulations). There were no compelling reasons presented by commenters to do otherwise. Therefore, we have retained proposed § 300.233(a)(1), without change, in these final regulations. The reasons for taking this position were specified in the preamble to the NPRM (and are also included in a new Appendix C to these Part 300 regulations). We believe that the regulations clearly indicate that, while States may provide additional funds to LEAs from their section 611(f) set-aside, only section 611(g) funds are subject to the 20 percent rule.

Changes: None.

Comment: A commenter noted that the NPRM did not indicate at what point in the year an LEA should make its calculation (*e.g.,* at the beginning of the year or at another time), and added that the point in time when the determination is made could have an impact on the LEA, especially if the LEA has had funds withheld that are later restored. The commenter further requested that the background section from the NPRM be expanded to include more complex examples for calculating

the 20 percent formula, and to specify resources in the Department that LEAs might turn to for assistance in this regard.

Discussion: The LEA may make its calculation—and spend the 20 percent of the increase in the Federal grant as local funds—at any point from the time the LEA receives its grant under section 611(g) of the Act (§ 300.712 of the regulations), to the end of the period that these funds are available for obligation. Thus, if an LEA's Federal fiscal year 2001 funds were withheld at the beginning of a school year, but were subsequently released by the SEA on January 1, 2002, the LEA could do the calculation and spend those funds any time between January 1, 2002 and September 30, 2003.

We agree with the commenter's request for additional examples. We also believe that it is important to retain, on a permanent basis, the background section from the NPRM related to the 20 percent rule (along with the examples), so that school officials at both the State and local levels will have a technical assistance source to turn to regarding implementation of that provision. Thus, we have included the basic content of the background section in the NPRM (with examples) in a new Appendix C to the regulations for this part.

With respect to providing technical assistance on the 20 percent rule at the Federal level, we believe that it would be more appropriate for LEAs to seek advice and guidance from the SEA within each State regarding implementation of the 20 percent rule, rather than directly seeking assistance from the Department. Because each SEA is responsible for monitoring an LEA's compliance with the Part B requirements (including the 20 percent rule), it would not be appropriate for the Department to provide direct assistance to individual LEAs on this provision. On the other hand, if the SEA, in assisting an LEA to apply the 20 percent rule, needs policy guidance regarding the provision, it would be appropriate for the SEA to contact the Department for that assistance.

Changes: A new Appendix C has been added to the regulations, as described in the preceding discussion.

Comment: One commenter stated that the preamble to the NPRM suggests that the 20 percent rule would be implemented beginning with fiscal year (FY) 2000, even though FY 1999 was the first year in which the section 611 appropriation exceeded $4.1 billion. The commenter added that the statutory authority relating to this provision was established by the IDEA Amendments of 1997, and, therefore, it would be inappropriate for the regulation to exclude the FY 1999 appropriation.

Discussion: Because funds for FY 1999 had already been received (and, in many cases already obligated by LEAs), we believed that it would be inappropriate to apply this amendment to § 300.233 retroactively to FY 1999 funds). Therefore, we proposed to apply the amended regulation to FY 2000 funds and thereafter. In the NPRM, we should have definitively stated that the FY 1999 appropriation was not affected by the proposed regulations, and, therefore, States and LEAs could apply a broader interpretation of section 613(a)(2)(C) of the Act (§ 300.233 of the regulations) to the funds they received from that appropriation.

Changes: None.

Comment: A commenter disagreed with the interpretation of the year by year applicability of the 20 percent rule in the NPRM, and stated that the provision should apply throughout the entire period of appropriations availability, including the carryover year authorized by the Tydings Amendment. The commenter further recommended that the regulation be revised to allow for the 20 percent rule to be applied on a cumulative basis, so that (for example) if there is no increase in appropriations for FY 2002 from the prior year, an LEA that has not used the 20 percent rule in fiscal years 1999, 2000, and 2001 would be allowed to take advantage of the appropriations increases received in those prior years for local budgetary relief.

Discussion: An LEA can take advantage of the 20 percent rule at any point throughout the period in which the LEA can use its section 611(g) funds, including the carryover year under the Tydings Amendment. (The Tydings Amendment allows States to obligate their grant funds for one additional year after the initial period of availability. See General Education Provisions Act, section 421.) However, there is no statutory authority to allow the provision to be applied on a cumulative basis. The Act makes it clear that the provision applies only on a year to year basis (*i.e.,* section 613(a)(2)(C) specifies that, for any fiscal year for which the amounts appropriated to carry out section 611 exceeds $4.1 billion, an LEA ''may treat as local funds * * * up to 20 percent of the amount of funds it receives under this part *that exceeds the amount it received under this part for the previous fiscal year.*''). Emphasis added.

Changes: None.

Comment: A commenter stated that § 300.233(a)(3) of the NPRM—which provides that an LEA is not eligible to receive funds that have been withheld under § 300.197 or § 300.587—is overbroad, and ignores the fact that funds that have been withheld may subsequently be released when compliance has been achieved. The commenter recommended that the provision be deleted, noting, further, that it does not coincide with section 613(a)(2)(C)(ii) of the Act (§ 300.233(b) of the regulations), which provides that an SEA may prohibit an LEA from applying the 20 percent rule only if it is authorized to do so by State constitution or statute.

Discussion: We agree with the commenter that proposed new § 300.233(a)(3) does not appropriately reflect the requirements of the Act. It should have indicated that funds that have been withheld may subsequently be released when compliance has been achieved, and that the 20 percent rule may be applied to those funds during their period of availability. This is consistent with our intent in the NPRM. However, we continue to believe that it is necessary to provide guidance in this area.

Upon further review of proposed § 300.233(a)(3), we believe that it needs to be revised to clarify that during any period in which Part B funds are withheld from an LEA because of a finding of noncompliance under § 300.197 or § 300.587, the LEA may not implement the 20 percent rule. However, if the funds are subsequently released to the LEA during the grant award period, the LEA may spend those funds consistent with the 20 percent rule.

Changes: Section 300.233(c) has been amended, consistent with the preceding discussion.

Executive Order 12866

We have reviewed these final regulations in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with the final regulations are those we have determined as necessary for administering these programs effectively and efficiently. Elsewhere in this **SUPPLEMENTARY INFORMATION** section, we identify and explain any burdens specifically associated with the information collection requirements. See the heading Paperwork Reduction Act of 1995.

In assessing the potential costs and benefits—both quantitative and

qualitative—of this regulatory action, we have determined that the benefits would justify the costs.

We summarized the potential costs and benefits of these final regulations in the preamble to the NPRM (65 FR 30314).

We have also determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Regulatory Flexibility Act Certification

The Secretary certifies that these final regulations will not have significant economic impact on a substantial number of small entities. The small entities affected will be small LEAs. The regulations will benefit the small entities affected by clarifying the statutory requirements and reducing the possibility of audit exceptions. By ensuring consistency, the regulations will promote more effective and efficient program administration.

Paperwork Reduction Act of 1995

These final regulations do not contain any information collection requirements.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, we intend this document to provide early notification of our specific plans and actions for this program.

Federalism

Executive Order 13132 requires us to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. ''Federalism implications'' means 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.

Since these regulations relate solely to implementation of the statutory 20 percent rule, we do not believe these regulations have federalism implications as defined in Executive Order 13132. In addition, these regulations do not preempt State law. Accordingly, the Secretary has determined that these final regulations do not contain policies that have federalism implications or that preempt State law.

Assessment of Educational Impact

In the NPRM, we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Based on the response to the NPRM and on our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

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(Catalog of Federal Domestic Assistance Number: 84.027 Assistance to States for the Education of Children with Disabilities)

List of Subjects

Administrative practice and procedure, Education of individuals with disabilities, Elementary and secondary education, Equal educational opportunity, Grant programs—education, Privacy, Private schools, Reporting and recordkeeping requirements.

Dated: December 12, 2000.

Richard W. Riley,

Secretary of Education.

For the reasons described in the preamble, the Secretary amends title 34, part 300, of the Code of Federal Regulations as follows:

PART 300—ASSISTANCE TO STATES FOR THE EDUCATION OF CHILDREN WITH DISABILITIES PROGRAM

1. The authority citation for part 300 continues to read as follows:

Authority: 20 U.S.C. 1411—1420, unless otherwise noted.

2. Section 300.233 is amended by revising paragraph (a)(1), and by adding a new paragraph (a)(3), to read as follows:

§ 300.233 Treatment of Federal funds in certain fiscal years.

(a)(1) Subject to paragraphs (a)(2), (a)(3), and (b) of this section, for any fiscal year for which amounts appropriated to carry out section 611 of the Act exceed $4.1 billion, an LEA may treat as local funds up to 20 percent of the amount of funds it is eligible to receive under § 300.712 from that appropriation that exceeds the amount from funds appropriated for the previous fiscal year that the LEA was eligible to receive under § 300.712.

* * * * *

(3) For purposes of this section:

(i)(A) An LEA is not eligible to receive funds during any period in which those funds under this part are withheld from the LEA because of a finding of noncompliance under § 300.197 or § 300.587.

(B) An LEA is eligible to receive funds that have been withheld under § 300.197 or § 300.587 but are subsequently released to the LEA within the period of the funds availability.

(ii) An LEA is not eligible to receive funds that have been reallocated to other LEAs under § 300.714.

3. Part 300 is further amended by adding a new Appendix C—Implementation of the 20 Percent Rule under § 300.233, to read as follows:

APPENDIX C TO PART 300—IMPLEMENTATION OF THE 20 PERCENT RULE UNDER § 300.233

This appendix is intended to assist States and LEAs to implement the ''20 percent rule'' under Part B (section 613(a)(2)(C)) of the Individuals with Disabilities Education Act (IDEA), and, specifically, the regulation implementing that provision in § 300.233. The purposes of the appendix are to—(1) provide background information about the 20 percent rule and its intended effect, including specifying which funds under Part B of the Act are covered by the provision (as described in § 300.233), and the basis for the Department's decision regarding those funds; and (2) include examples showing how the 20 percent rule would apply in several situations.

A. Background

1. *Purpose of 20 Percent Rule.* The IDEA Amendments of 1997 (Pub. L. 105–17) added

a provision related to the permissive treatment of a portion of Part B funds by LEAs for maintenance of effort and non-supplanting purposes in certain fiscal years (see section 613(a)(2)(C) of the Act and § 300.233). Under that provision, for any fiscal year (FY) for which the appropriation for section 611 of IDEA exceeds $4.1 billion, an LEA may treat as local funds, for maintenance of effort and non-supplanting purposes, up to 20 percent of the amount it receives that exceeds the amount it received under Part B during the prior year.

Thus, under § 300.233, an LEA is able to meet the maintenance of effort requirement of § 300.231 and the non-supplanting requirement of § 300.230(c) even though it reduces the amount it spends of other local or local and State funds, as the case may be, by an amount equal to the amount of Federal funds that may be treated as local funds.

2. *20 Percent Rule Applies Only to LEA Subgrants.* Following enactment of the IDEA Amendments of 1997 (and publication of Part B regulations on March 12, 1999), State and local educational agency officials stated that it is not clear from the Act and regulations whether the funds affected by the 20 percent rule are only those that an LEA receives through statutory subgrants under section 611(g), or whether the provision also applies to other Part B funding sources (*i.e.*, subgrants to LEAs for capacity-building and improvement under section 611(f)(4); other funds the SEA may provide to LEAs under section 611(f); or funds provided under section 619 (Preschool Grants program)).

Further, because section 613(a)(2)(C) refers to an amount of funds that an LEA ''receives'' in one fiscal year compared to the amount it ''received'' in the prior fiscal year (and because agencies may, at any one point in time, be using funds appropriated in several Federal fiscal years), agency officials were uncertain as to how to determine that an LEA had ''received'' Federal funds.

Because the statute and regulations were not sufficiently clear with respect to which precise funds are affected by the 20 percent rule, this could have resulted in the provision being interpreted and applied differently from LEA to LEA. If that situation were to occur, it could result in a significant increase in the number of audit exceptions against LEAs.

Given the confusion about which funding sources are affected by the 20 percent rule, there was a critical need to set out in the regulations a clear interpretation of section 613(a)(2)(C) in order to support its consistent application across LEAs and States, and to reduce the potential for audit exceptions. Thus, on June 10, 2000, the Department published a notice of proposed rulemaking (NPRM) regarding this provision (65 FR 30314). The NPRM stated that—

In light of the statutory structure for distribution of Federal funds to LEAs, we believe that the most reasonable interpretation is to apply that provision *only to subgrants to LEAs under section 611(g)* of the Act (§ 300.712 of the regulations) from funds appropriated from one Federal fiscal year compared to funds appropriated for the prior Federal fiscal year. (Emphasis added.)

Thus, the NPRM proposed to exclude the other Federal funds under Part B of the Act (*i.e.,* Subgrants to LEAs for capacity-building and improvement under section 611(f)(4) (§ 300.622); other funds the SEA may provide to LEAs under section 611(f) (§ 300.602); and preschool grant funds under section 619 (34 CFR part 301)) from the funds that could be treated as local funds. The reasons for excluding these other Part B funds were stated in the NPRM, as follows:

- If IDEA funds that States have the authority to provide to LEAs on a discretionary basis (such as those identified in the preceding paragraph) are included in the 20 percent calculation, it would result in some LEAs receiving a proportionately greater benefit from this provision than other LEAs, based on receipt of funds that may be earmarked for a specific, time-limited purpose. This would lead to inequitable results of the § 300.233 exception across LEAs in a State.
- Including section 619 formula grant funds (34 CFR part 301) in the calculation does not appear to be justified as the ''trigger'' appropriation amount applies only with respect to the amount appropriated under section 611.

The Department subsequently determined that the position taken in the NPRM (that the provision under § 300.233 should apply only to LEA subgrant funds under section 611(g) of the Act) is the most appropriate and reasonable position to follow in implementing the 20 percent rule. Therefore, the proposed provision in § 300.233(a)(1) was retained, without change, in the final regulations.

B. Application of the 20 percent rule

1. Examples Related to Implementing the 20 percent rule

The following are examples showing how the 20 percent provision would apply under several situations:

- *Example 1:* An LEA receives $100,000 in Federal LEA Subgrant funds under section 611(g) of the Act from the appropriation for one fiscal year (FY–1), and $120,000 in section 611(g) funds from the appropriation for the following fiscal year (FY–2). The LEA may spend and treat as local funds up to 20 percent of the $20,000 in section 611(g) funds it receives from FY–2 (i.e., up to $4,000), since this is the amount that exceeds the amount it received from the prior year.
- *Example 1–A:* In Example 1, an LEA in FY–2 is uncertain whether to exercise its option to treat as local funds during FY–2 up to $4,000 of its section 611(g) funds received from FY–2, and wishes to wait until the carry-over year to make a decision. If the LEA decides to exercise its option during the carry-over period regarding the $4,000 from the FY–2 appropriation, it could do so as long as those funds are used within the carry-over period for FY–2.
- *Example 1–B:* An LEA receives $100,000 in section 611(g) funds from FY–1, $120,000 from FY–2 and $140,000 from FY–3. The LEA may spend and treat as local funds up to 20 percent of the $20,000 from FY–2 funds and $20,000 of FY–3 funds (*i.e.,* up to $4,000 for each year). Thus, if its FY–2 funds are not used until FY–3, and the LEA so chooses, it may spend and treat as local funds during FY–3 a total of up to $8,000 in section 611(g) funds (*i.e.,* $4,000 from FY–2 and $4,000 from FY–3), provided those funds are obligated by the end of FY–3.
- *Example 2:* An LEA from one fiscal year (FY–1) receives $100,000 in section 611(g) funds and $20,000 in SEA discretionary funds under section 611(f) of the Act; and from the following year (FY–2) receives $120,000 in section 611(g) funds, but does not receive any funds under section 611(f). The LEA may spend and treat up to 20 percent of the $20,000 in section 611(g) funds it receives from FY–2 (i.e. up to $4,000), since $20,000 is the amount of section 611(g) funds that exceeds the amount it received from FY–1.
- *Example 3:* An LEA had all of its section 611(g) funds ($100,000) withheld from one fiscal year (FY–1); but in the next fiscal year (FY–2), the LEA received a total of $220,000 in section 611(g) funds (*i.e.,* $100,000 from FY–1, plus $120,000 from FY–2). Because the LEA would have been entitled to $100,000 in FY–1, the LEA may spend and treat as local funds up to 20 percent of the $20,000 from FY–2 that exceeded the FY–1 allotment (*i.e.,* up to $4,000).
- *Example 4:* An LEA received $100,000 under section 611(g) from one fiscal year (FY–1), and would have received $120,000 in section 611(g) funds for the next fiscal year (FY–2); but the LEA has had all of its section 611(g) funds withheld in FY–2 because of a finding of noncompliance under § 300.197 or § 300.587. The LEA would have no section 611(g) funds that could be spent or treated as local funds until those funds are released.
- *Example 4–A:* In example 4, the SEA subsequently determines that the LEA is in compliance, and releases the FY–2 funds to the LEA later in that fiscal year. The LEA could then spend and treat as local funds up to 20 percent of the $20,000 that exceeds the amount it received in FY–1 (i.e., up to $4,000). Those funds could be used by the LEA for the remainder of FY–2 and through the end of the carry-over period for FY–2 funding.

2. Auditing for Compliance with § 300.231 and the 20 percent rule in § 300.233

The following provides guidance for use by auditors in determining if LEAs are in compliance with the maintenance of effort requirement in § 300.231 and the 20 percent rule in § 300.233:

a. *Meeting the Maintenance of Effort Requirement.* In order to be eligible to receive an IDEA-Part B subgrant in any particular fiscal year, an LEA is required to demonstrate that it has budgeted an amount of State and local funds, or just local funds, to be spent on special education and related services that equals or exceeds (on either an aggregate or per capita basis) the amount of those funds spent by the LEA for those purposes in the prior fiscal year, or in the most recent prior fiscal year for which information is available. 34 CFR 300.231.

b. *Auditing Compliance with § 300.231.* Auditors, in determining if an LEA has complied with § 300.231 in any particular fiscal year, review the actual level of expenditures of State and local funds, or just local funds, on special education and related services for the year in question and the prior

year. For example, consider an LEA that, in the LEA's FY–1, spent a total of $1,000,000 of local funds on special education and related services to serve 100 students with disabilities. (For this discussion, assume that the LEA does not receive any State funds for any year for special education and related services.) An auditor, in trying to determine if the LEA, in its FY–2, had complied with § 300.231, would review the LEA's expenditure of local funds on special education and related services. If, in the LEA's FY–2, the LEA served 100 students with disabilities and spent $1,000,000 or more in local funds on special education and related services, it would have met the requirements of § 300.231 for FY–2.

c. *Application of the 20 percent rule to § 300.231.* If the LEA in the preceding example had spent only $996,000 of local funds on special education and related services for its 100 students with disabilities in its FY–2 (not counting any section 611(g) subgrant funds that could be considered local funds under the 20 percent rule), then it would have failed to meet its obligation under § 300.231, and an auditor would question $4,000 of the LEA's IDEA-Part B subgrant expenditures in that year.

This questioned cost, however, could be avoided, if the LEA had available, and spent, $4,000 of Federal funds under the 20 percent rule during its FY–2. These funds may be available from a variety of sources (see Examples in paragraph 1). If, as described in Example 1 of paragraph 1 the LEA had received from the Federal FY–2 appropriation, a section 611(g) subgrant that was $20,000 greater than the subgrant it received from the Federal FY–1 appropriation, then up to $4,000 of that subgrant could be treated as local funds. The LEA, however, would have to spend at least $4,000 of its Federal FY–2 section 611(g) subgrant during its FY–2 in order for those funds to count as part of its local expenditures for that year for purposes of § 300.231.

In this example, if the LEA had carried over all of its Federal FY–2 section 611(g) subgrant to the LEA's FY–3 (and thus did not spend any of those funds during its FY–2), then none of the section 611(g) subgrant funds subject to the 20 percent rule could be considered as local funds for purposes of determining compliance with § 300.231. (The reason for this is that auditors, in determining an LEA's compliance with § 300.231, examine State and local, or local funds the LEA actually spent on special education and related services, and *not* those funds that the LEA could, but did not, spend for those purposes.)

If the LEA, in its FY–2, spent $4,000 of its Federal FY–2 section 611(g) subgrant, then the LEA could count those expenditures and bring itself into compliance with § 300.231 (i.e., $996,000 of the LEA's own local funds spent on special education and related services plus the $4,000 of Federal FY–2 section 611(g) funds that can be counted as local funds equals a total of $1,000,000 of local expenditures on special education in its FY–2—the amount of local expenditures needed to comply with § 300.231). However, if the LEA elected to take this step, it could not count any of the Federal FY–2 section 611(g) subgrant funds that it will spend in its FY–3 as local funds.

If the LEA, in its FY–2, spent only $3,000 of its Federal FY–2 section 611(g) subgrant funds, then those funds could be counted by the LEA as local funds in calculating its compliance with § 300.231 for its FY–2. If the remaining $1,000 of Federal FY–2 funds available to be considered local funds were spent in the LEA's FY–3, those funds could be considered in determining the LEA's compliance with § 300.231 for its FY–3. (Note, However, that if in its FY–2 the LEA had only spent $996,000 of local funds and $3,000 of its Federal funds, it would not have met the requirements of § 300.231. In this case the auditor would have $1,000 of questioned costs ($1,000,000 − [$996,000+$3,000]=$1,000) for FY–2).

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Federal Register

Monday,
January 8, 2001

Part VII

Department of Education

Office of Special Education and Rehabilitative Services, National Institute on Disability and Rehabilitation Research; Inviting Applications and Pre-application for a New Disability and Rehabilitation Research Projects for Fiscal Year 2001–2002; Final Funding Priorities for Fiscal Years 2001–2002 for a National Center on Accessible Education-Based Information Technology and the Disability and Business Technical Assistance Centers; Notices

DEPARTMENT OF EDUCATION

[CFDA No.: 84.133D]

Office of Special Education and Rehabilitative Services, National Institute on Disability and Rehabilitation Research; Notice Inviting Applications and Pre-application for a New Disability and Rehabilitation Research Projects for Fiscal Year 2001–2002

Note to Applicants: This notice is a complete application package. Together with the statute authorizing the programs and applicable regulations governing the programs including the Education Department General Administrative Regulations (EDGAR), this notice contains information, application forms, and instructions needed to apply for a grant under these competitions.

These programs support the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

The estimate of funding levels in this notice does not bind the Department of Education to make awards in any of these categories, or to any specific number of awards or funding levels, unless otherwise specified in statute.

Requests for funding reasonable accommodations are not included in the maximum award amount, per year, as listed in the table.

Reasonable Accommodation: We will consider, and may grant, requests for additional funding as an addendum to an application to reflect the costs of reasonable accommodations necessary to allow individuals with disabilities to be employed on the project as personnel on project activities.

This notice also invites interested parties to participate in a pre-application meeting to discuss the funding priorities for a National Center on Accessible Education-Based Information Technology and the Disability and Business Technical Assistance Centers and to receive technical assistance through individual consultation and information about the funding priority. The pre-application meeting will be held on Wednesday, February 14, 2001 at the Department of Education, Office of Special Education and Rehabilitative Services, Switzer Building, Room 3065, 330 C St. SW, Washington, DC between 9:30 a.m. and 12:00 a.m. NIDRR staff will also be available at this location from 1:30 p.m. to 5:00 p.m. on that same day to provide technical assistance through individual consultation and information about the funding priority. NIDRR will make alternate arrangements to accommodate interested parties who are unable to attend the pre-application meeting in person. For further information contact Joseph DePhillips, Switzer Building, room 3418, 330 C Street, SW, Washington, D.C. 20202. Telephone (202) 205–8187. If you use a TTY, please call (202) 205–4475.

Assistance to Individuals With Disabilities at the Public Meeting

The meeting site is accessible to individuals with disabilities, and a sign language interpreter will be available. If you need an auxiliary aid or service other than a sign language interpreter in order to participate in the meeting (e.g. other interpreting service such as oral, cued speech, or tactile interpreter; assistive listening device; or materials in alternative format), notify the contact person listed in this notice at least two weeks before the scheduled meeting date. Although we will attempt to meet a request we receive after this date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Purpose of the Program: One of the purposes of the Disability and Rehabilitation Research Projects and Centers Program is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973. The Assistant Secretary takes this action to focus research attention on an area of national need. The priority is intended to improve rehabilitation services and outcomes for individuals with disabilities.

The notice of final funding priorities for a National Center on Accessible Education-Based Information Technology and the Disability and Business Technical Assistance Centers is published elsewhere in this issue of the **Federal Register**.

Eligible Applicants: Parties eligible to apply for grants under this program are States, public or private agencies, including for-profit agencies, public or private organizations, including for-profit organizations, institutions of higher education, and Indian tribes and tribal organizations.

Application Available: January 8, 2001.

Project Period: 60 months.

Program Authority: 29 U.S.C. 762(g) and 764(b)(4).

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR), 34 CFR parts 74, 75, 77, 80, 81, 82, 85, and 86; the program regulations 34 CFR part 350, and the Notice of Final Priority published elsewhere in this issue of the **Federal Register**.

APPLICATION NOTICE FOR FISCAL YEARS 2000–2001 DISABILITY AND REHABILITATION RESEARCH PROJECTS, CFDA NO. 84–133D

Funding priority	Deadline for transmittal of applications	Estimated number of awards	Maximum award amount (per year)*	Project period (months)
84.133D National Center on Accessible Education-Based Information Technology.	March 26, 2001	1	$700,000	60
84.133–D8 Disability and Business Technical Assistance Centers.	March 26, 2001	see below	See below (Break down by Region).	60
Region I, DBTAC	March 26, 2001	1	$850,000	60
Region II, DBTAC	March 26, 2001	1	$1,100,000	60
Region III, DBTAC	March 26, 2001	1	$1,100,000	60
Region IV, DBTAC	March 26, 2001	1	$1,450,000	60
Region V, DBTAC	March 26, 2001	1	$1,450,000	60
Region VI, DBTAC	March 26, 2001	1	$1,100,000	60
Region VII, DBTAC	March 26, 2001	1	$850,000	60
Region VIII, DBTAC	March 26, 2001	1	$850,000	60
Region IX, DBTAC	March 26, 2001	1	$1,450,000	60
Region X, DBTAC	March 26, 2001	1	$850,000	60

APPLICATION NOTICE FOR FISCAL YEARS 2000–2001 DISABILITY AND REHABILITATION RESEARCH PROJECTS, CFDA NO. 84–133D—Continued

Funding priority	Deadline for transmittal of applications	Estimated number of awards	Maximum award amount (per year)*	Project period (months)
AIMS (optional)	March 26, 2001	1	$80,000	60

***Note:** Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year.

For Applications Contact: The Grants and Contracts Service Team (GCST), Department of Education, 400 Maryland Avenue SW, Switzer Building, 3317, Washington, D.C. 20202, or call (202) 205–8207. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–9860. The preferred method for requesting information is to FAX your request to (202) 205–8717.

Individuals with disabilities may obtain a copy of the application package in an alternative format by contacting the GCST. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

FOR FURTHER INFORMATION CONTACT: Donna Nangle, U.S. Department of Education, 400 Maryland Avenue, SW, room 3414, Switzer Building, Washington, D.C. 20202–2645. Telephone: (202) 205–5880. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–4475. Internet: Donna_Nangle@ed.gov.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

Selection Criteria

National Center on Accessible Education-Based Information

Technology Selection Criteria: The Secretary uses the following selection criteria to evaluate applications for the National Center on Accessible Education-Based Information Technology.

(a) *Importance of the problem* (3 points total). (1) The Secretary considers the importance of the problem.

(2) In determining the importance of the problem, the Secretary considers the extent to which the proposed project will have beneficial impact on the target population (3 points).

(b) *Design of training activities* (24 points total). (1) The Secretary considers the extent to which the design of training activities is likely to be effective in accomplishing the objectives of the project.

(2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Secretary considers the following factors:

(i) The extent to which the proposed training materials are likely to be effective, including consideration of their quality, clarity, and variety (17 points).

(ii) The extent to which the proposed training methods are of sufficient quality, intensity, and duration (7 points).

(c) *Design of dissemination activities* (24 points total).

(1) The Secretary considers the extent to which the design of dissemination activities is likely to be effective in accomplishing the objectives of the project.

(2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Secretary considers the following factors:

(i) The extent to which the materials to be disseminated are likely to be effective and usable, including consideration of their quality, clarity, variety, and format (17 points).

(ii) The extent to which the methods for dissemination are of sufficient quality, intensity, and duration (7 points).

(d) *Design of technical assistance activities* (22 points total). (1) The Secretary considers the extent to which the design of technical assistance activities is likely to be effective in accomplishing the objectives of the project.

(2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Secretary considers the following factors:

(i) The extent to which the methods for providing technical assistance are of sufficient quality, intensity, and duration (7 points).

(ii) The extent to which the information to be provided through technical assistance covers all of the relevant aspects of the subject matter (15 points).

(e) *Quality of the management plan* (3 points total). (1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (3 points).

(f) *Adequacy and reasonableness of the budget* (4 points total). (1) The Secretary considers the adequacy and the reasonableness of the proposed budget.

(2) In determining the adequacy and the reasonableness of the proposed budget, the Secretary considers the following factors:

(i) The extent to which the costs are reasonable in relation to the proposed project activities (2 points).

(iii) The extent to which the budget for the project, including any subcontracts, is adequately justified to support the proposed project activities (2 points).

(g) *Quality of the project evaluation* (3 points total).

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project (3 points).

(h) *Project staff* (13 points total). (1) The Secretary considers the quality of the project staff.

(2) In determining the quality of the project staff, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (1 point).

(3) In addition, the Secretary considers the following factors:

(i) The extent to which key personnel have expert knowledge on the American with Disabilities Act (ADA) and experience with providing technical assistance on the ADA to conduct all proposed activities (3 points).

(ii) The extent to which key personnel have expert knowledge about state-of-the-art Information Technology (IT) to conduct all proposed activities (7 points).

(iii) The extent to which the commitment of staff time is adequate to accomplish all the proposed activities of the project (2 points).

(i) *Adequacy and accessibility of resources* (4 points total). (1) The Secretary considers the adequacy and accessibility of the applicant's resources to implement the proposed project.

(2) In determining the adequacy and accessibility of resources, the Secretary considers the following factors:

(i) The extent to which the applicant is committed to provide adequate facilities, equipment, other resources, including administrative support, and laboratories, if appropriate (2 points).

(ii) The extent to which the facilities, equipment, and other resources are appropriately accessible to individuals with disabilities who may use the facilities, equipment, and other resources of the project (2 points).

The Disability and Business Technical Assistance Centers

Selection Criteria: The Secretary uses the following selection criteria to evaluate applications for the Disability and Business Technical Assistance Centers.

(a) *Importance of the problem* (3 points total). (1) The Secretary considers the importance of the problem.

(2) In determining the importance of the problem, the Secretary considers the extent to which the proposed project will have beneficial impact on the target population (3 points).

(b) *Significance* (3 points total). (1) The Secretary considers the significance of the proposed project.

(3) In determining the significance of the proposed project, the Secretary considers the extent to which the proposed project is likely to build local capacity to provide, improve, or expand services that address the needs of the target population (3 points).

(c) *Design of training activities* (14 points total). (1) The Secretary considers the extent to which the design of training activities is likely to be effective in accomplishing the objectives of the project.

(2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Secretary considers the following factors:

(i) The extent to which the proposed training materials are likely to be effective, including consideration of their quality, clarity, and variety (7 points).

(ii) The extent to which the proposed training methods are of sufficient quality, intensity, and duration (7 points).

(d) *Design of dissemination activities* (21 points total).

(1) The Secretary considers the extent to which the design of dissemination activities is likely to be effective in accomplishing the objectives of the project.

(2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Secretary considers the following factors:

(i) The extent to which the materials to be disseminated are likely to be effective and usable, including consideration of their quality, clarity, variety, and format (7 points).

(ii) The extent to which the methods for dissemination are of sufficient quality, intensity, and duration (7 points).

(iii) The extent to which the materials and information to be disseminated and the methods for dissemination are appropriate to the target population, including consideration of the familiarity of the target population with the subject matter, format of the information, and subject matter (7 points).

(e) *Design of technical assistance activities* (21 points total). (1) The Secretary considers the extent to which the design of technical assistance activities is likely to be effective in accomplishing the objectives of the project.

(2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Secretary considers the following factors:

(i) The extent to which the methods for providing technical assistance are of sufficient quality, intensity, and duration (7 points).

(iii) The extent to which the information to be provided through technical assistance covers all of the relevant aspects of the subject matter (7 points).

(iii) The extent to which the technical assistance is appropriate to the target population, including consideration of the knowledge level of the target population, needs of the target population, and format for providing information (7 points).

(f) *Quality of project services* (10 points total). (1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (2 points).

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services (5 points).

(ii) The extent to which the technical assistance services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources (3 points).

(g) *Quality of the management plan* (3 points total). (1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (3 points).

(h) *Adequacy and reasonableness of the budget* (4 points total). (1) The Secretary considers the adequacy and the reasonableness of the proposed budget.

(2) In determining the adequacy and the reasonableness of the proposed budget, the Secretary the following factors:

(i) The extent to which the costs are reasonable in relation to the proposed project activities (2 points).

(ii) The extent to which the budget for the project, including any subcontracts, is adequately justified to support the proposed project activities (2 points).

(i) *Quality of the project evaluation* (3 points total). (1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and

outcomes of the proposed project (3 points).

(j) *Project staff* (14 points total). (1) The Secretary considers the quality of the project staff.

(2) In determining the quality of the project staff, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (1 point).

(3) In addition, the Secretary considers the following factors:

(i) The extent to which key personnel have expert knowledge on the ADA and experience with providing technical assistance on the ADA to conduct all proposed activities (8 points).

(ii) The extent to which key personnel have expert knowledge about state-of-the-art IT to conduct all proposed activities (3 points).

(iii) The extent to which the commitment of staff time is adequate to accomplish all the proposed activities of the project (2 points).

(k) *Adequacy and accessibility of resources* (4 points total). (1) The Secretary considers the adequacy and accessibility of the applicant's resources to implement the proposed project.

(2) In determining the adequacy and accessibility of resources, the Secretary considers the following factors:

(i) The extent to which the applicant is committed to provide adequate facilities, equipment, other resources, including administrative support, and laboratories, if appropriate (2 points).

(ii) The extent to which the facilities, equipment, and other resources are appropriately accessible to individuals with disabilities who may use the facilities, equipment, and other resources of the project (2 points).

Additional Selection Criterion: The maximum score for all the criteria is 100 points; however, under 34 CFR 75.105(c)(2)(i) we will also use the following criterion so that up to an additional 10 points may be earned by an applicant for a total possible score of 110 points.

Up to 10 points based on the extent to which an application includes effective strategies for employing and advancing in employment qualified individuals with disabilities in projects awarded under these absolute priorities. In determining the effectiveness of those strategies, we will consider the applicant's prior success, as described in the application, in employing and advancing in employment qualified individuals with disabilities.

Thus, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for these priorities. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Instructions for Application Narrative

The Secretary will reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount per year (See 34 CFR 75.104(b)).

The Secretary strongly recommends the following:

(1) A one-page abstract;

(2) An Application Narrative (*i.e.,* Part III that addresses the selection criteria that will be used by reviewers in evaluating individual proposals) of no more 125 pages for Project applications, double-spaced (no more than 3 lines per vertical inch) 8″ x 11″ pages (on one side only) with one inch margins (top, bottom, and sides). The application narrative page limit recommendation does not apply to: Part I—the electronically scannable form; Part II—the budget section (including the narrative budget justification); and Part IV—the assurances and certifications; and

(3) A font no smaller than a 12-point font and an average character density no greater than 14 characters per inch.

Instructions for Transmittal of Applications

(a) If an applicant wants to apply for a grant, the applicant must—

(1) Mail the original and two copies of the application on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # [Applicant must insert number and letter] and name), Washington, DC 20202–4725, or

(2) Hand deliver the original and two copies of the application by 4:30 p.m. [Washington, DC time] on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # [Applicant must insert number and letter] and name), Room #3633, Regional Office Building #3, 7th and D Streets, SW., Washington, DC.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Notes: (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) An applicant wishing to know that its application has been received by the Department must include with the application a stamped self-addressed postcard containing the CFDA number and title of this program.

(3) The applicant must indicate on the envelope and—if not provided by the Department—in Item 10 of the Application for Federal Assistance (Standard Form 424) the CFDA number—and letter, if any—of the competition under which the application is being submitted.

Application Forms and Instructions

The appendix to this application is divided into four parts. These parts are organized in the same manner that the submitted application should be organized. These parts are as follows:

PART I: Application for Federal Assistance (ED Form 424 (Rev. 11/12/99)) and instructions.

PART II: Budget Form—Non-Construction Programs (ED Form 524A) and instructions.

PART III: Application Narrative.

Additional Materials

Estimated Public Reporting Burden.

Assurances—Non-Construction Programs (Standard Form 424B).

Certification Regarding Lobbying, Debarment, Suspension, and Other Responsibility Matters: and Drug-Free Work-Place Requirements (ED Form 80–0013).

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED Form 80–0014) and instructions. (NOTE: ED Form GCS–014 is intended for the use of primary participants and should not be transmitted to the Department.)

Disclosure of Lobbying Activities (Standard Form LLL (if applicable) and instructions; and Disclosure Lobbying Activities Continuation Sheet (Standard Form LLL–A).

An applicant may submit information on a photostatic copy of the application and budget forms, the assurances, and the certifications. However, the application form, the assurances, and the certifications must each have an original signature. No grant may be

awarded unless a completed application form has been received.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news.html

To use PDF you must have Adobe Acrobat Reader, which is available free at either of the preceding sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at:

http://www.access.gpo.gov/nara/index.html

(Catalog of Federal Domestic Assistance Numbers: 84.133D, Disability and Rehabilitation Research Projects)

Program Authority: 29 U.S.C. 762(g) and 764(b)(4).

Dated: December 26, 2000.

Curtis L. Richards,

Acting Assistant Secretary For Special Education and Rehabilitative Services.

Appendix

Application Forms and Instructions

Applicants are advised to reproduce and complete the application forms in this section. Applicants are required to submit an original and two copies of each application as provided in this section. However, applicants are encouraged to submit an original and seven copies of each application in order to facilitate the peer review process and minimize copying errors.

Frequest Questions

1. Can I Get an Extansion of the Due Date?

No! On rare occasions the Department of Education may extend a closing date for all applicants. If that occurs, a notice of the revised due date is published in the **Federal Register**. However, there are no extensions or exceptions to the due date made for individual applicants.

2. What Should Be Included in the Application?

The application should include a project narrative, vitae of key personnel, and a budget, as well as the Assurances forms included in this package. Vitae of staff or consultants should include the individual's title and role in the proposed project, and other information that is specifically pertinent to this proposed project. The budgets for both the first year and all subsequent project years should be included.

If collaboration with another organization is involved in the proposed activity, the application should include assurances of participation by the other parties, including written agreements or assurances of cooperation. It is not useful to include general letters of support or endorsement in the application.

If the applicant proposes to use unique tests or other measurement instruments that are not widely known in the field, it would be helpful to include the instrument in the application.

Many applications contain voluminous appendices that are not helpful and in many cases cannot even be mailed to the reviewers. It is generally not helpful to include such things as brochures, general capability statements of collaborating organizations, maps, copies of publications, or descriptions of other projects completed by the applicant.

3. What Format Should Be Used for the Application?

NIDRR generally advises applicants that they may organize the application to follow the selection criteria that will be used. The specific review criteria vary according to the specific program, and are contained in this Consolidated Application Package.

4. May I Submit Applications to More Than One NIDRR Program Competition or More Than One Application to a Program?

Yes, you may submit applications to any program for which they are responsive to the program requirements. You may submit the same application to as many competitions as you believe appropriate. You may also submit more than one application in any given competition.

5. What Is the Allowable Indirect Cost Rate?

The limits on indirect costs vary according to the program and the type of application.

An applicant for a Disability and Rehabilitation Research Project should limit indirect charges to the organization's approved indirect cost rate. If the organization does not have an approved indirect cost rate, the application should include an estimated actual rate.

6. Can Profitmaking Businesses Apply for Grants?

Yes. However, for-profit organizations will not be able to collect a fee or profit on the grant, and in some programs will be required to share in the costs of the project.

7. Can Individuals Apply for Grants?

No. Only organizations are eligible to apply for grants under NIDRR programs. However, individuals are the only entities eligible to apply for fellowships.

8. Can NIDRR Staff Advise Me Whether My Project is of Interest to NIDRR or Likely to be Funded?

No. NIDRR staff can advise you of the requirements of the program in which you propose to submit your application. However, staff cannot advise you of whether your subject area or proposed approach is likely to receive approval.

9. How Do I Assure That My Application Will be Referred to the Most Appropriate Panel for Review?

Applicants should be sure that their applications are referred to the correct competition by clearly including the competition title and CFDA number, including alphabetical code, on the ED Form 424, and including a project title that describes the project.

10. How Soon After Submitting My Application Can I Find Out if it Will be Funded?

The time from closing date to grant award date varies from program to program. Generally speaking, NIDRR endeavors to have awards made within five to six months of the closing date. Unsuccessful applicants generally will be notified within that time frame as well. For the purpose of estimating a project start date, the applicant should estimate approximately six months from the closing date, but no later than the following September 30.

11. Can I Call NIDRR to Find Out if My Application is Being Funded?

No. When NIDRR is able to release information on the status of grant applications, it will notify applicants by letter. The results of the peer review cannot be released except through this formal notification.

12. If My Application is Successful, Can I Assume I Will Get the Requested Budget Amount in Subsequent Years?

No. Funding in subsequent years is subject to availability of funds and project performance.

13. Will All Approved Applications be Funded?

No. It often happens that the peer review panels approve for funding more applications than NIDRR can fund within available resources. Applicants who are approved but not funded are encouraged to consider submitting similar applications in future competitions.

BILLING CODE 4000–01–U

Application for Federal Education Assistance

Note: If available, please provide application package on diskette and specify the file format.

U.S. Department of Education

Form Approved
OMB No. 1875-0106
Exp. 06/30/2001

Applicant Information

1. Name and Address
Legal Name:
Address:
City State County ZIP Code + 4

Organizational Unit

2. Applicant's D-U-N-S Number
3. Applicant's T-I-N
4. Catalog of Federal Domestic Assistance #: 8 4
Title:
5. Project Director:
Address:
City State ZIP Code + 4
Tel. #: ( ) Fax #: ( )
E-Mail Address:

6. Is the applicant delinquent on any Federal debt? Yes No
(If "Yes," attach an explanation.)

7. Type of Applicant *(Enter appropriate letter in the box.)*

A State	H Independent School District
B County	I Public College or University
C Municipal	J Private, Non-Profit College or University
D Township	K Indian Tribe
E Interstate	L Individual
F Intermunicipal	M Private, Profit-Making Organization
G Special District	N Other *(Specify)*:

8. Novice Applicant Yes No

Application Information

9. Type of Submission:

—PreApplication	*—Application*
Construction	Construction
Non-Construction	Non-Construction

10. Is application subject to review by Executive Order 12372 process?
Yes *(Date made available to the Executive Order 12372 process for review):* ___/___/___
No *(If "No," check appropriate box below.)*
Program is not covered by E.O. 12372.
Program has not been selected by State for review.

11. Proposed Project Dates: Start Date: ___/___/___ End Date: ___/___/___

12. Are any research activities involving human subjects planned at any time during the proposed project period? Yes No
a. If "Yes," Exemption(s) #:
OR
b. Assurance of Compliance #:
c. IRB approval date:
Full IRB **or** Expedited Review

13. Descriptive Title of Applicant's Project:

Estimated Funding

14a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

Authorized Representative Information

15. To the best of my knowledge and belief, all data in this preapplication/application are true and correct. The document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached assurances if the assistance is awarded.

a. Typed Name of Authorized Representative
b. Title
c. Tel. #: ( ) Fax #: ( )
d. E-Mail Address:
e. **Signature of Authorized Representative** Date: ___/___/___

REV. 11/12/99

ED 424

Instructions for ED 424

1. **Legal Name and Address.** Enter the legal name of applicant and the name of the primary organizational unit which will undertake the assistance activity.

2. **D-U-N-S Number.** Enter the applicant's D-U-N-S Number. If your organization does not have a D-U-N-S Number, you can obtain the number by calling 1-800-333-0505 or by completing a D-U-N-S Number Request Form. The form can be obtained via the Internet at the following URL: **http://www.dnb.com/dbis/aboutdb/intlduns.htm.**

3. **Tax Identification Number.** Enter the tax identification number as assigned by the Internal Revenue Service.

4. **Catalog of Federal Domestic Assistance (CFDA) Number.** Enter the CFDA number and title of the program under which assistance is requested.

5. **Project Director.** Name, address, telephone and fax numbers, and e-mail address of the person to be contacted on matters involving this application.

6. **Federal Debt Delinquency.** Check **"Yes"** if the applicant's organization is delinquent on any Federal debt. (This question refers to the applicant's organization and not to the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.) Otherwise, check **"No."**

7. **Type of Applicant.** Enter the appropriate letter in the box provided.

8. **Novice Applicant.** Check **"Yes"** only if assistance is being requested under a program that gives special consideration to novice applicants and you meet the program requirements for novice applicants. By checking "Yes" the applicant certifies that it meets the novice applicant requirements specified by ED. Otherwise, check **"No."**

9. **Type of Submission.** Self-explanatory.

10. **Executive Order 12372.** Check **"Yes"** if the application is subject to review by Executive Order 12372. Also, please enter the month, date, and four (4) digit year (e.g., 12/12/2000). Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. Otherwise, check **"No."**

11. **Proposed Project Dates.** Please enter the month, date, and four (4) digit year (e.g., 12/12/2000).

12. **Human Subjects.** Check "Yes" **or** "No". If research activities involving human subjects are **not** planned **at any time** during the proposed project period, check **"No." The remaining parts of item 12 are then not applicable.**

    If research activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, **are** planned **at any time** during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check **"Yes."** If **all** the research activities are designated to be exempt under the regulations, enter, in item 12a, the exemption number(s) corresponding to one or more of the six exemption categories listed in **"Protection of Human Subjects in Research"** attached to this form. Provide sufficient information in the application to allow a determination that the designated exemptions in item 12a, are appropriate. **Provide this narrative information in an "Item 12/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page. Skip the remaining parts of item 12.**

    If **some or all** of the planned research activities involving human subjects are covered (nonexempt), skip item 12a and continue with the remaining parts of item 12, as noted below. In addition, follow the instructions in **"Protection of Human Subjects in Research"** attached to this form to prepare the six-point narrative about the nonexempt activities. **Provide this six-point narrative in an "Item 12/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

    If the applicant organization has an approved Multiple Project Assurance of Compliance on file with the Grants Policy and Oversight Staff (GPOS), U.S. Department of Education, or with the Office for Protection from Research Risks (OPRR), National Institutes of Health, U.S. Department of Health and Human Services, that covers the specific activity, enter the Assurance number in item 12b and the date of approval by the Institutional Review Board (IRB) of the proposed activities in item 12c. This date must be no earlier than one year before the receipt date for which the application is submitted and must include the four (4) digit year (e.g., 2000). Check the type of IRB review in the appropriate box. An IRB may use the expedited review procedure if it complies with the requirements of 34 CFR 97.110. If the IRB review is delayed beyond the submission of the application, enter **"Pending"** in item 12c. If your application is recommended/selected for funding, a follow-up certification of IRB approval from an official signing for the applicant organization must be sent to and received by the designated ED official within 30 days after a specific formal request from the designated ED official. **If the applicant organization does not have** on file with GPOS or OPRR **an approved Assurance of Compliance** that covers the proposed research activity, enter **"None"** in item 12b and skip 12c. In this case, the applicant organization, by the signature on the application, is declaring that it will comply with 34 CFR 97 within 30 days after a specific formal request from the designated ED official for the Assurance(s) and IRB certifications.

13. **Project Title.** Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

14. **Estimated Funding.** Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate **only** the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 14.

15. **Certification.** To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office.

    Be sure to enter the telephone and fax number and e-mail address of the authorized representative. Also, in item 15e, please enter the month, date, and four (4) digit year (e.g., 12/12/2000) in the date signed field.

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **1875-0106**. The time required to complete this information collection is estimated to average between 15 and 45 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the estimate(s) or suggestions for improving this form, please write to:** U.S. Department of Education, Washington, D.C. 20202-4651. **If you have comments or concerns regarding the status of your individual submission of this form write directly to:** Joyce I. Mays, Application Control Center, U.S. Department of Education, 7th and D Streets, S.W. ROB-3, Room 3633, Washington, D.C. 20202-4725.

PROTECTION OF HUMAN SUBJECTS IN RESEARCH (Attachment to ED 424)

I. Instructions to Applicants about the Narrative Information that Must be Provided if Research Activities Involving Human Subjects are Planned

If you marked item 12 on the application "Yes" and designated exemptions in 12a, **(all research activities are exempt),** provide sufficient information in the application to allow a determination that the designated exemptions are appropriate. Research involving human subjects that is exempt from the regulations is discussed under **II.B. "Exemptions,"** below. The Narrative must be succinct. **Provide this information in an "Item 12/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

If you marked "Yes" to item 12 on the face page, and designated no exemptions from the regulations **(some or all of the research activities are nonexempt),** address the following six points for each nonexempt activity. In addition, if research involving human subjects will take place at collaborating site(s) or other performance site(s), provide this information before discussing the six points. Although no specific page limitation applies to this section of the application, be succinct. Provide the six-point narrative and discussion of other performance sites in an **"Item 12/Protection of Human Subjects Attachment" and insert this attachment immediately following the ED 424 face page.**

(1) Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

(2) Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(3) Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

(4) Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

(5) Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(6) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

II. Information on Research Activities Involving Human Subjects

A. Definitions.

A research activity involves human subjects if the activity is research, as defined in the Department's regulations, and the research activity will involve use of human subjects, as defined in the regulations.

—Is it a research activity?

The ED Regulations for the Protection of Human Subjects, Title 34, Code of Federal Regulations, Part 97, define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." *If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.* Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

—Is it a human subject?

The regulations define human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." *(1) If an activity involves obtaining information about a living person by manipulating that person or that person's environment, as might occur when a new instructional technique is tested, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met. (2) If an activity involves obtaining private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information), the definition of human subject is met.* [Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a school health record).]

B. Exemptions.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories of ***exemptions*** are not covered by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. ***If the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*** [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S Department of Agriculture.

Copies of the Department of Education's Regulations for the Protection of Human Subjects, 34 CFR Part 97 and other pertinent materials on the protection of human subjects in research are available from the Grants Policy and Oversight Staff (GPOS) Office of the Chief Financial and Chief Information Officer, U.S. Department of Education, Washington, D.C., telephone: (202) 708-8263, and on the U.S. Department of Education's Protection of Human Subjects in Research Web Site at http://ocfo.ed.gov/humansub.htm.

U.S. DEPARTMENT OF EDUCATION

BUDGET INFORMATION

NON-CONSTRUCTION PROGRAMS

OMB Control Number: 1890-0004

Expiration Date: 02/28/2003

Name of Institution/Organization

Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

SECTION A - BUDGET SUMMARY
U.S. DEPARTMENT OF EDUCATION FUNDS

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

ED Form No. 524

Name of Institution/Organization	Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

SECTION B - BUDGET SUMMARY
NON-FEDERAL FUNDS

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

SECTION C - OTHER BUDGET INFORMATION (see instructions)

ED Form No. 524

Public reporting burden for this collection of information is estimated to vary from 13 to 22 hours per response, with an average of 17.5 hours per response, including the time reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202-4651; and the Office of Management and Budget, Paperwork Reduction Project 1875-0102, Washington DC 20503.

INSTRUCTIONS FOR ED FORM 524

General Instructions

This form is used to apply to individual U.S. Department of Education discretionary grant programs. Unless directed otherwise, provide the same budget information for each year of the multi-year funding request. Pay attention to applicable program specific instructions, if attached.

Section A - Budget Summary
U.S. Department of Education Funds

All applicants must complete Section A and provide a breakdown by the applicable budget categories shown in lines 1-11.

Lines 1-11, columns (a)-(e): For each project year for which funding is requested, show the total amount requested for each applicable budget category.

Lines 1-11, column (f): Show the multi-year total for each budget category. If funding is requested for only one project year, leave this column blank.

Line 12, columns (a)-(e): Show the total budget request for each project year for which funding is requested.

Line 12, column (f): Show the total amount requested for all project years. If funding is requested for only one year, leave this space blank.

Section B - Budget Summary
Non-Federal Funds

If you are required to provide or volunteer to provide matching funds or other non-Federal resources to the project, these should be shown for each applicable budget category on lines 1-11 of Section B.

Lines 1-11, columns (a)-(e): For each project year for which matching funds or other contributions are provided, show the total contribution for each applicable budget category.

Lines 1-11, column (f): Show the multi-year total for each budget category. If non-Federal contributions are provided for only one year, leave this column blank.

Line 12, columns (a)-(e): Show the total matching or other contribution for each project year.

Line 12, column (f): Show the total amount to be contributed for all years of the multi-year project. If non-Federal contributions are provided for only one year, leave this space blank.

Section C - Other Budget Information
Pay attention to applicable program specific instructions, if attached.

1. Provide an itemized budget breakdown, by project year, for each budget category listed in Sections A and B.

2. If applicable to this program, enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period. In addition, enter the estimated amount of the base to which the rate is applied, and the total indirect expense.

3. If applicable to this program, provide the rate and base on which fringe benefits are calculated.

4. Provide other explanations or comments you deem necessary.

ESTIMATED PUBLIC REPORTING BURDEN

Public reporting burden for these collections of information is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of these collections of information, including suggestions for reducing this burden, to: the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202-4651; and to the Office of Management and Budget, Paperwork Reduction Project 1820-0027, Washington, D.C. 20503.

Disability and Rehabilitation Research Projects (CFDA No. 84.133A) 34 CFR Part 350 Subpart B.

OMB Approval No. 0348-0040

ASSURANCES - NON-CONSTRUCTION PROGRAMS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0040), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

NOTE: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant, I certify that the applicant:

1. Has the legal authority to apply for Federal assistance and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§4728-4763) relating to prescribed standards for merit systems for programs funded under one of the 19 statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§290 dd-3 and 290 ee 3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and, (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§276a to 276a-7), the Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§327-333), regarding labor standards for federally-assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. §§7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and, (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. §470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. §§2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.) which prohibits the use of lead-based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act Amendments of 1996 and OMB Circular No. A-133, "Audits of States, Local Governments, and Non-Profit Organizations."

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE

APPLICANT ORGANIZATION	DATE SUBMITTED

CERTIFICATIONS REGARDING LOBBYING; DEBARMENT, SUSPENSION AND OTHER RESPONSIBILITY MATTERS; AND DRUG-FREE WORKPLACE REQUIREMENTS

Applicants should refer to the regulations cited below to determine the certification to which they are required to attest. Applicants should also review the instructions for certification included in the regulations before completing this form. Signature of this form provides for compliance with certification requirements under 34 CFR Part 82, "New Restrictions on Lobbying," and 34 CFR Part 85, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." The certifications shall be treated as a material representation of fact upon which reliance will be placed when the Department of Education determines to award the covered transaction, grant, or cooperative agreement.

1. LOBBYING

As required by Section 1352, Title 31 of the U.S. Code, and implemented at 34 CFR Part 82, for persons entering into a grant or cooperative agreement over $100,000, as defined at 34 CFR Part 82, Sections 82.105 and 82.110, the applicant certifies that:

(a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;

(b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions;

(c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all subrecipients shall certify and disclose accordingly.

2. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS

As required by Executive Order 12549, Debarment and Suspension, and implemented at 34 CFR Part 85, for prospective participants in primary covered transactions, as defined at 34 CFR Part 85, Sections 85.105 and 85.110—

A. The applicant certifies that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this application been convicted of or had a civil judgement rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (2)(b) of this certification; and

(d) Have not within a three-year period preceding this application had one or more public transaction (Federal, State, or local) terminated for cause or default; and

B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.

3. DRUG-FREE WORKPLACE (GRANTEES OTHER THAN INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610 -

A. The applicant certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an on-going drug-free awareness program to inform employees about:

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency, in writing, within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to: Director, Grants Policy and Oversight Staff, U.S. Department of Education, 400 Maryland Avenue, S.W. (Room 3652, GSA Regional Office Building No. 3), Washington, DC 20202-4248. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address. city, county, state, zip code)

_____

_____

_____

Check [ ] if there are workplaces on file that are not identified here.

DRUG-FREE WORKPLACE (GRANTEES WHO ARE INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610-

A. As a condition of the grant, I certify that I will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant; and

B. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, I will report the conviction, in writing, within 10 calendar days of the conviction, to: Director, Grants Policy and Oversight Staff, Department of Education, 400 Maryland Avenue, S.W. (Room 3652, GSA Regional Office Building No. 3), Washington, DC 20202-4248. Notice shall include the identification number(s) of each affected grant.

As the duly authorized representative of the applicant, I hereby certify that the applicant will comply with the above certifications.

NAME OF APPLICANT	PR/AWARD NUMBER AND / OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE

ED 80-0013 12/98

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion — Lower Tier Covered Transactions

This certification is required by the Department of Education regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, for all lower tier transactions meeting the threshold and tier requirements stated at Section 85.110.

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," " person," "primary covered transaction," " principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion-Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may but is not required to, check the Nonprocurement List.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

NAME OF APPLICANT	PR/AWARD NUMBER AND/OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE

ED 80-0014, 9/90 (Replaces GCS-009 (REV.12/88), which is obsolete)

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action: ☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	**2. Status of Federal Action:** ☐ a. bid/offer/application b. initial award c. post-award	**3. Report Type:** ☐ a. initial filing b. material change **For Material Change Only:** year _____ quarter _____ date of last report _____
4. Name and Address of Reporting Entity: ☐ Prime ☐ Subawardee Tier _____, *if known*: **Congressional District**, *if known*:	**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:** **Congressional District**, *if known*:	
6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable*: _____	
8. Federal Action Number, *if known*:	**9. Award Amount**, *if known*: $	
10. a. Name and Address of Lobbying Registrant (*if individual, last name, first name, MI*):	**b. Individuals Performing Services** (*including address if different from No. 10a*) (*last name, first name, MI*):	
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less that $10,000 and not more than $100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____	
Federal Use Only:		Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348-0046. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, DC 20503.

[FR Doc. 01–85 Filed 1–4–01; 8:45 am]
BILLING CODE 4000–01–C

DEPARTMENT OF EDUCATION

National Institute on Disability and Rehabilitation Research; Notice of Final Funding Priorities for Fiscal Years 2001–2002 for a National Center on Accessible Education-Based Information Technology and the Disability and Business Technical Assistance Centers

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

SUMMARY: The Assistant Secretary for the Office of Special Education and Rehabilitative Services announces final funding priorities for a National Center on Accessible Education-Based Information Technology and the Disability and Business Technical Assistance Centers under the National Institute on Disability and Rehabilitation Research (NIDRR) for fiscal years 2001–2002. The Assistant Secretary takes this action to focus research attention on areas of national need. We intend these priorities to improve the rehabilitation services and

outcomes for individuals with disabilities.

DATES: These priorities take effect on February 7, 2001.

FOR FURTHER INFORMATION CONTACT: Donna Nangle. Telephone: (202) 205–5880. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–4475. Internet: donna_nangle@ed.gov.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION: This notice contains final priorities under the Disability and Rehabilitation Research Projects and Centers Program (DRRP) for a National Center on Accessible Education-Based Information Technology and the Disability and Business Technical Assistance Centers.

The final priorities refer to NIDRR's Long Range Plan (the Plan). The Plan can be accessed on the World Wide Web at: *http://www.ed.gov/offices/OSERS/NIDRR/#LRP.*

National Education Goals

These final priorities will address the National Education Goal that every adult American will be literate and will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

The authority for the program to establish research priorities by reserving funds to support particular research activities is contained in sections 202(g) and 204 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 762(g) and 764(b)(4)). Regulations governing this program are found in 34 CFR part 350.

Note: This notice does not solicit applications. A notice inviting applications is published in this issue of the **Federal Register**.

Analysis of Comments and Changes

On November 7, 2000, the Assistant Secretary published a notice of proposed priorities in the **Federal Register** (65 FR 66732). The Department of Education received 10 letters commenting on the notice of proposed priorities by the deadline date. Technical and other minor changes—and suggested changes the Assistant Secretary is not legally authorized to make under statutory authority—are not addressed.

Disability and Rehabilitation Research Project and Centers Program

General Comments

Comment: The National Center on Accessible Education-Based Information Technology or one of the DBTACs should be responsible for evaluating the accessibility of nationally distributed IT products.

Discussion: The scale of this activity would rival all of the required activities in the priority. In addition, a variety of public and private sector interests (*e.g.,* manufacturers, Federal agencies, trade associations, disability organizations) currently undertake this activity. The National Center and the DBTACs will disseminate the results of these evaluations. We decline to revise the priority as suggested because of its scale and in order to avoid duplication of effort.

Changes: None.

Comment: An additional factor was proposed to the selection criteria that will be used to evaluate applications for the National Center and the DBTACs. This proposed factor states that in determining the quality of the project staff, NIDRR will consider the extent to which key personnel have expert knowledge about state-of-the-art IT to conduct all activities.

One commenter suggested that this factor should be revised to include the extent to which key personnel have expert knowledge about the ADA and significant experience in providing technical assistance about basic and complex ADA issues.

A second commenter suggested that this factor should be applied to all partners and collaborators in an application.

Discussion: In regard to the first comment, it will not be possible for the National Center and the DBTACs to fulfill their purposes unless key personnel have expert knowledge on the ADA and experience with providing technical assistance on the ADA. Revising the selection criteria as suggested by the first commenter will improve the evaluation process. We agree to revise the factor as suggested.

In regard to the second comment, the application of this factor is not restricted exclusively to the applicant. The staff of an applicant's partners or collaborators will be evaluated by the peer reviewers using this factor if their roles are considered key to the performance of the grant. It is not necessary to revise the factor in order to address the commenter's concern.

Changes: The selection criteria have been changed to include a factor that addresses the extent to which key personnel have expert knowledge on the ADA and experience with providing technical assistance on the ADA.

National Center on Accessible Education-Based Information Technology

Comment: The National Center should be required to coordinate with the Assistive Technology Act Projects and the Technical Assistance provider to the Assistive Technology Act Projects.

Discussion: The priority requires the National Center to coordinate with a number of NIDRR grantees as well as a wide array of Federal agencies. Because we do not believe that it is imperative for the National Center to coordinate with the Assistive Technology Act Projects and the Technical Assistance provider to the Assistive Technology Act Projects in order to fulfill the purposes of the priority, we decline to require the National Center to coordinate with these entities. However, an applicant may propose to coordinate with the Assistive Technology Act Projects and the Technical Assistance provider to the Assistive Technology Act Projects, and the application review process will evaluate the merits of the proposal.

Changes: None.

Disability and Business Technical Assistance Centers

Comment: Two commenters suggested requiring the DBTACs to provide technical assistance on the nondiscrimination requirements of the Workforce Investment Act to entities within the Workforce Investment System such as One-Stop Centers and local Workforce Investment Boards.

Discussion: Other than educational entities, the priority does not require the DBTACs to provide technical assistance and training to any specific target audience. In order to allow the DBTACs as much flexibility as possible to meet the demands for technical assistance within their region, we decline to require the DBTACs to provide technical assistance and training to entities within the Workforce Development System. The priority allows the DBTACs the discretion to provide technical assistance to all entities covered by the ADA including those within the Workforce Investment System. An applicant may propose to provide technical assistance and training to entities within the Workforce Development System, and the application review process will evaluate the merits of the proposal.

Changes: None.

Comment: Three commenters made various suggestions to require the DBTACs to promote the employment status of persons with disabilities. Two commenters suggested that the DBTACs should be required to promote best practices in the employment area for business and government. One of these commenters also suggested that an additional selection criteria factor be added to evaluate applicants' proposals to promote successful employer practices that impact hiring, retention, and promotion of persons with disabilities.

Two commenters suggested that the DBTACs undertake a number of activities to educate employers and employment specialists on providing accessible IT to employees with disabilities and the benefits of providing this accommodation.

Discussion: One of the primary purposes of the ADA is to prohibit discrimination against persons with disabilities in the area of employment in order to improve their employment status. Nearly twenty-five percent of all the training and technical assistance that the DBTACs provide is targeted to employers and businesses. The DBTACs have the authority to undertake the types of activities submitted by the commenters. We believe that they are excellent activities to promote the successful implementation of the ADA. However, in order to provide the DBTACs with as much flexibility as possible in meeting the needs of their regions, we decline to revise the selection criteria or require these specific activities. An applicant may propose to undertake the activities suggested by the commenters, and the application review process will evaluate the merits of the proposal.

Changes: None.

Comment: The priority adds a special emphasis to the mission of the DBTACs, by requiring them to assist educational entities in providing children, youth, and adults with disabilities with access to IT. Five commenters expressed various concerns about these activities.

Three commenters observed that these activities departed significantly from the DBTACs' primary mission. One of these commenters suggested this activity emphasis could compromise the DBTACs' principal efforts in providing technical assistance and training on the ADA. The other two commenters suggested that the DBTACs did not possess the requisite experience in working with IT and State and local educational entities to be effective. These latter two commenters, as well as two additional commenters, suggested that the Assistive Technology Act State grantees would be more effective than the DBTACs in carrying out these activities.

Discussion: We share the first commenter's concern that the special emphasis should not compromise the technical assistance and training that the DBTACs provide on the ADA. In order to ensure that this does not happen, we requested and received an increase of approximately five million dollars in the DBTAC program's budget. We believe that this additional support will allow the DBTACs to maintain their current level of activity on the ADA and effectively carry out the additional activities related to accessible education-based IT.

In regard to the commenters who questioned whether the DBTACs were the appropriate vehicle to carry out the special emphasis, the DBTAC program has had a special emphasis on working with schools systems dating back to 1994 and has developed a State network structure that is well-suited to delivering training and technical assistance at the State and local levels. In order to ensure that the DBTACs have the technological expertise on IT that will be necessary to successfully carry out the special emphasis, we designed the priority and the selection criteria to require the DBTACs to partner with organizations that are expert in IT and maintain IT expertise on their staffs.

In regard to the comment that the Assistive Technology State grantees would be more effective than the DBTACs in carrying out this special emphasis, NIDRR recognizes the valuable contribution that these organizations can make to this initiative. This is evidenced by the fact that the priority specifically requires the DBTACs to form regional partnerships with the Assistive Technology Act grantees among others. We note that the entities that administer the Assistive Technology State grants are eligible applicants for the DBTAC competition. NIDRR encourages competition in all of our programs, and looks forward to receiving applications from a wide range of applicants with the capabilities to fulfill the purposes of a DBTAC.

Changes: None.

Comment: The DBTACs should be required to utilize the personnel from the Assistive Technology Act Project and the Office of Special Education Program's Regional Resource Centers.

Discussion: We decline to specify applicant personnel because applicants should be able to tailor proposed personnel to the activities that will be supported. An applicant may propose to utilize personnel from the Assistive Technology Act Project and the Office of Special Education Program's Regional Resource Centers, and the application review process will evaluate the merits of the proposal.

Changes: None.

Comment: Educational IT is unique in many respects and is developed by an industry that is diverse and not very advanced in addressing accessibility standards. Providing technical assistance and training to schools without a complementary effort targeted toward industry will minimize the impact of the priority.

Discussion: We agree with the commenter's observations regarding the unique qualities of educational IT and the need to work with industry to improve the accessibility of their IT products. NIDRR has funded a Rehabilitation Engineering Research Center (RERC) on Information Technology Access since June of 1998, an Information Technology Technical Assistance and Training Center in FY2000, and plans on establishing a new RERC on Wireless Information Technology in FY2001. The mission of both of these RERCs is to work closely with industry to assist them in the development and marketing of accessible IT products. When these centers work with the educational IT industry, they will address the unique qualities of educational IT products. Therefore we believe that this priority is appropriately focused with an emphasis on education-based information technology.

Changes: None.

Comment: Two commenters expressed concern about the lack of national standards and its impact on the technical assistance provided by the DBTACs. One of these commenters suggested that NIDRR should wait for national standards for accessibility to computer labs to be developed before providing technical assistance and training to educational entities.

Discussion: National accessibility standards, including those for computer labs, would simplify the work of the DBTACs significantly. However, educational entities need technical assistance now in order to improve the accessibility of their IT. We decline to wait to provide technical assistance and training.

Changes: None.

Comment: Elementary and secondary schools are accustomed to using the Individuals with Disabilities Education Act (IDEA) and Section 504 to understand their obligation to provide accessible instructional technology to students with disabilities. It will be helpful to not only seek a clear legal interpretation of the ADA's

requirements for accessible IT, but also to connect that obligation to IDEA and Section 504.

Discussion: As indicated in the background to the priority, covered entities often seek technical assistance to understand the relationship between related disability laws. In order for the DBTACs to be able to provide the type of technical assistance identified by the commenter, the priority requires the DBTACs to be knowledgeable about a wide array of disability-related or disability rights laws, including IDEA and Section 504. In addition, the priority emphasizes the importance of the DBTACs' promotion of best practices in order to encourage educational entities to acquire accessible IT even when they are not obligated to do so. Therefore, no changes are necessary to address the commenter's concern regarding 504 and IDEA because we expect the DBTACs to be able to assist schools to understand not only their ADA obligations, but also the relationships between the ADA, IDEA, and Section 504.

In regard to the comment of the need for clear legal interpretation of the ADA's requirements for IT, as case law and policy guidance from responsible Federal agencies develop on the subject of the application of the ADA to IT, the DBTACs will disseminate this information to all interested parties.

Changes: None.

Comment: Does education-based IT include accessible textbooks and accessibility issues related to instructional media (*e.g.,* captioning and audio description of video)?

Discussion: The final paragraph of the introduction to the two priorities provides definitions of IT and education-based IT. If the textbooks and instructional media contemplated by the commenter meet the definition of IT cited in this paragraph, then they would be considered education-based IT.

Changes: None.

Disability and Rehabilitation Research Project and Centers Program

The authority for Disability and Rehabilitation Research Projects (DRRP) is contained in section 204 of the Rehabilitation of 1973, as amended (29 U.S.C. 762(g) and 764(b)(4)). The purpose of the Disability and Rehabilitation Research Project and Centers Program is to plan and conduct research, demonstration projects, training and related activities to—

(a) Develop methods, procedures, and rehabilitation technology that maximizes the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities; and

(b) Improve the effectiveness of services authorized under the Act.

Priorities on the ADA and Accessible Education-Based Information Technology (IT)

Public Law 101–336, the Americans with Disabilities Act (ADA), enacted on July 26, 1990, prohibits discrimination against individuals with disabilities in employment, public accommodations, transportation, State and local government, and telecommunications. In October 1991, and again in October 1996, NIDRR awarded five-year grants to establish 10 regional Disability and Business Technical Assistance Centers (DBTACs). These centers provide technical assistance and training on all of the requirements of the ADA to covered entities and individuals with responsibilities and rights under the ADA. Currently, there is one DBTAC in each of the 10 Department of Education regions. For FY 2001 NIDRR is funding 10 new DBTACs that will maintain the current level of effort on providing information and technical assistance on the ADA as well as add a special emphasis in the area of education-based information technology (IT). The purpose of this special emphasis is to assist covered educational entities in providing children, youth, and adults with disabilities with access to IT.

NIDRR is funding two priorities toward this end. The first will establish a national center on accessible education-based IT that will operate in collaboration with the DBTACs and will provide support and guidance on education-based accessible IT technical assistance activities. The second priority will establish 10 new DBTACs and delineates the technical assistance and training activities required of them to promote the successful implementation of the ADA, including those activities related to the special emphasis on educational institutions and accessible IT.

For the purposes of these priorities, and consistent with the Clinger-Cohen Act of 1996, information technology is defined to include any equipment or interconnected system or subsystem of equipment that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. It includes computer hardware, software, networks, and peripherals as well as many electronic and communications devices commonly used in offices. Education-based IT refers to any IT that is used by either students or employees of educational entities, including, but not limited to, teachers, administrators, and administrative staff.

Priority 1: National Center on Accessible Education-Based IT

Background

IT plays a critical role in all educational settings. Regardless of their age, students who cannot access IT are operating at a significant disadvantage to their peers who can. Recent reports suggests that, regardless of age, educators and students with disabilities face significant IT accessibility issues (''Computer and Internet Use Among People with Disabilities,'' Dr. Stephen Kaye, Disability Statistics Center, University of California-San Francisco, published by NIDRR, U.S. Department of Education, March 2000; and ''What are the Barriers to Use of Advanced Telecommunications for Students with Disabilities in Public Schools,'' Issue Brief published by the National Center for Education Statistics, U.S. Department of Education, NCES 2000–42, January 2000). These issues can be broken down into two types: legal and technological.

Section 504 of the Rehabilitation Act of 1973, as amended, prohibits discrimination on the basis of disability in any program or activity of recipients of Federal financial assistance. Virtually all school districts receive Federal funds and have been required to comply with Section 504 for many years. The ADA extends this prohibition to a wider range of educational entities; however, with some exceptions, the ADA does not impose any major new requirements on school districts and other educational entities that receive Federal funds and are covered by Section 504.

The ADA requires virtually all educational entities to ensure that persons with disabilities are not excluded from participation in, or denied the benefits of, its services, programs, and activities. This includes all aspects of the instructional environment, employment relationships, and services carried out by contractors. When IT is part of the programs, services, or activities provided by the educational entity, those entities have an obligation to ensure that the hardware and software that make up those technologies are accessible to all users. In some instances, educational entities may be unaware of their legal obligation to provide accessible IT to persons with disabilities who enroll or seek to enroll in their programs. Similarly, persons with disabilities may be unaware that

they are entitled under the ADA to access the IT of the educational entity.

It may also be the case that educational entities do not have the information they need to either purchase accessible IT, or adapt the IT they have so that it is accessible to students or employees with disabilities. Both the responsible party within the educational entity (*e.g.,* the procurement officer, related services personnel, the teacher, or the computer lab director) and the student, or employee with a disability, may be unaware that accessible IT exists and can be purchased, or that adaptations may be made to the existing IT to provide accessibility. When a student or employee with a disability uses assistive technology (*e.g.,* an augmentative communication device), the technological problem may involve identifying the proper interface between the educational entity's IT and the student or employee's assistive technology. In these instances, information and technical assistance can aid the educational entity to provide accessible IT.

Some educational entities may also be required to comply with the standards for accessible technology to be issued by the Access Board, as required by Section 508 of the Rehabilitation Act. Section 508 requires Federal agencies and departments to ensure equal access to electronic and information technology for individuals with disabilities comparable to those who do not have disabilities, unless such a requirement would cause an undue burden. The Assistive Technology Act (AT Act) requires that States receiving assistance, including sub-recipients of AT Act funds, under the AT State Grants program comply with the requirements of section 508, including the standards developed by the Access Board. Each State must determine whether entities such as colleges and universities or local and intermediate school districts are considered part of the State and therefore, must comply with Section 508 and the standards as published by the Access Board.

Priority 1: We will establish a National Center on Accessible Education-Based IT to assist educational entities in providing persons with disabilities with accessible IT. The Center must:

(1) Develop new materials and reformat or reprint existing materials to assist educational entities to understand and fulfill their legal obligations to provide accessible IT. These materials may include, but are not limited to, the ADA self-evaluation guide for schools, Section 504 and ADA guidance for educational entities, technical materials on IT access, consumers' guide to accessible IT, and technical IT standards;

(2) Conduct a national information dissemination campaign to raise awareness on accessible education-based IT and inform target audiences on the availability of technical assistance from the DBTACs and others. This campaign may include, but is not limited to, print and electronic ads, newsletters, presentations at national conferences, and regular electronic communication with national organizations to update them on legal and technological developments;

(3) Promote the procurement by educational entities of accessible information technology that meets the standards for section 508 or universal design principles;

(4) Coordinate with and provide training, materials, and technical assistance to the DBTACs in support of their technical assistance efforts to educational entities on accessible IT;

(5) Provide training, materials, and technical assistance to the U. S. Department of Education's various IT initiatives including, but not limited to, the Regional Technology in Education Consortia, Comprehensive Regional Assistance Centers, the Technology Literacy Challenge Fund, Community Technology Centers, and the Preparing Tomorrow's Teachers to Use Technology Programs in order to promote accessibility by persons with disabilities; and

In carrying out these activities, the National Center on Accessible Education-based IT must:

- Include in its primary target audience elementary and secondary institutions, and postsecondary educational entities including, but not limited to, institutions of higher education, proprietary schools (particularly those offering IT training), and adult education programs;
- Coordinate with NIDRR's Rehabilitation Engineering Research Centers (RERCs) on Information Technology Access and Telecommunications Access, and also with NIDRR's Information Technology Technical Assistance and Training Center;
- Coordinate with relevant Federal agencies responsible for the administration of public laws that address access to and usability of education-based IT for persons with disabilities including, but not limited, to the General Services Administration, the Access Board, the Federal Communications Commission, the Department of Justice, and offices within the Department of Education including the Rehabilitation Services Administration, the Office of Special Education Programs, and the Office for Civil Rights;
- Develop and maintain a web site to assist educational entities to understand and fulfill their legal obligations related to accessible IT; and
- Provide information and technical assistance consistent with other IT accessibility laws, including, but not limited to, section 508 of the Rehabilitation Act.

Priority 2: Disability and Business Technical Assistance Centers

Background

Covered entities and individuals with responsibilities and rights under the ADA continue to need technical assistance on the ADA. The demand for technical assistance services from the DBTACs has remained high since 1992 (see Table 1), a trend that will likely continue indefinitely.

TABLE 1.—SUMMARY OF SELECTED DBTAC TECHNICAL ASSISTANCE AND TRAINING ACTIVITIES FROM FY 1992 THROUGH FY 1999

Fiscal year	Number of 800 line calls	Number of people trained	Number of technical assistance efforts	Number of hard copy materials dissemi-nated
1992	20,000	30,759	40,313	188,842
1993	61,000	63,341	79,964	539,511
1994	75,700	56,800	127,736	698,040
1995	90,400	64,870	152,395	901,878

TABLE 1.—SUMMARY OF SELECTED DBTAC TECHNICAL ASSISTANCE AND TRAINING ACTIVITIES FROM FY 1992 THROUGH FY 1999—Continued

Fiscal year	Number of 800 line calls	Number of people trained	Number of technical assistance efforts	Number of hard copy materials disseminated
1996	88,500	64,502	135,000	1,800,000
1997	91,534	70,000	180,909	785,695
1998	92,312	86,000	157,126	1,082,294
1999	90,839	74,500	170,865	1,014,057

Source: Annual Reports of NIDRR's ADA Technical Assistance Grantees FY 1992–FY 1999.

In many instances, the nature of the technical assistance that the DBTACs provide today is more complex than the technical assistance they provided in the years shortly after the passage of the ADA. This is a result of covered entities seeking to stay current with the growing body of legal precedents as well as standards and policy guidance issued by responsible Federal agencies. However, there are still many covered entities that need information on the most fundamental requirements of the law. Subsequently, DBTACs must continue to provide basic information about the ADA as well as respond to more complex requests for technical assistance and training.

In order to be effective, it is virtually imperative that the DBTACs exploit the benefits of IT and stay current with new developments in the field. For example, the DBTACs use web-based programs to carry out distance learning activities in order to increase access to and participation in their information dissemination efforts. In FY 1999 the DBTACs and the ADA Program Assistance Coordinator's web sites received over 870,001 visits. While there will always be a need to distribute hard copies of materials, the DBTACs receive increasing numbers of requests for electronic copies of these same materials. They also respond to technical questions, provide training, and participate in cooperative efforts related to ADA technical assistance activities using electronic media. To carry out a wide variety of electronic and web-based technical assistance and training activities, the DBTACs' staffs must have a sufficiently high level of expertise on IT.

The DBTACs provide a wide range of technical assistance services such as referrals, consultation, and information dissemination. They also issue newsletters and information briefs, and participate in discussion groups on the Internet. The DBTACs address the needs of non-English populations by distributing materials that have been translated into other languages and employing bilingual information specialists when appropriate. Table 2 indicates the recipient groups of the DBTACs technical assistance, training, and materials distribution activities in FY 1999.

TABLE 2.—SUMMARY OF PERCENTAGE OF TECHNICAL ASSISTANCE, TRAINING, AND MATERIALS DISTRIBUTED TO TARGET AUDIENCE BY DBTACS IN FY 1999

Target audience	Technical assistance	Training	Materials distributions
Disability entities	50	44	45
Businesses	31	24	30
Public entities	14	23	18
Other	5	9	7

Source: Annual Report of NIDRR's ADA Technical Assistance Grantees FY 1999.

In addition, the DBTACs carry out public awareness activities on the ADA and the services provided by the DBTACs through a variety of means including, but not limited to, radio and television appearances, presentations at conferences, and the production of materials for newspaper and magazine articles. When it enhances their technical assistance activities, the DBTACs also disseminate ADA research findings generated by NIDRR-sponsored grantees and others.

In order to tailor their efforts to State and local needs and maximize their resources, DBTACs also work to increase the capacity of State and local organizations to provide technical assistance, disseminate information, provide training, and promote awareness of the ADA. The DBTACs have established at least one affiliate in every State. These affiliates carry out their activities in collaboration with coalitions of organizations interested in promoting the implementation of the ADA. In addition, the DBTACs support and collaborate with Centers for Independent Living (CILs) to assist them in implementing the ADA through the provision of technical assistance and training.

The DBTACs rely, to the maximum extent possible, on existing Federally-approved materials and, through a systematic process of quality control, ensure the legal sufficiency and accuracy of the information disseminated by the Centers and their affiliates. DBTAC services and activities are accessible to all individuals with disabilities, and all of the materials they distribute are available in alternate formats. The DBTACs also share a national toll-free telephone number that automatically connects the caller with the DBTAC serving the caller's area code. Further, the DBTACs meet semi-annually to coordinate their activities and receive briefings from Federal agencies with responsibilities under the ADA. They also evaluate their technical assistance efforts using the ADA Impact Measurement System (AIMS). AIMS uses a follow-up telephone survey and a postcard survey to measure the impact that the DBTACs' technical assistance has had on its customers and their level of satisfaction with the services that the DBTACs provided. AIMS are currently

maintained by one of the DBTACs. The proposed priority includes an optional activity authorizing a DBTAC to maintain AIMS over the proposed project period. From among those DBTAC applicants who propose to maintain AIMS over the project period, the application evaluation process will select one successful applicant to carry out this activity.

Since 1991, the DBTACs have provided technical assistance and training to educational entities on their responsibilities under the ADA. In 1994, NIDRR funded a training project on the ADA for schools and supported the U.S. Department of Education Office for Civil Rights' development and publication of an ADA self-evaluation guide for public elementary and secondary schools. A toll-free ADA hotline specifically for school systems, that originated with the schools training project, is still in operation through the Region I DBTAC. The special emphasis that is being placed on the DBTACs to provide technical assistance on accessible IT to educational entities represents an expansion of their technical assistance efforts. In those instances where the requisite assistance is a matter of helping the entity to understand its legal obligation, NIDRR expects the DBTACs to provide accurate information to the educational entity on the requirements of the ADA. In those instances where the requisite assistance is technical and involves assisting the entity to procure, create, adapt, maintain or evaluate the accessibility of their IT, NIDRR expects the DBTACs to possess the requisite technical expertise or develop partnerships with agencies and organizations who have the necessary technical expertise.

The DBTACs routinely receive inquiries that involve disability-related laws or disability rights laws other than the ADA. In some of these instances, the inquiry concerns the interaction between the ADA and disability-related laws such as the Family and Medical Leave Act or the Worker's Compensation Act. In other instances, individuals with a disability may believe that their civil rights have been violated, but are not sure of the controlling authority. For example, individuals with a disability may want to know about their landlord's responsibility to make their apartment accessible. In this case, in order to provide appropriate technical assistance, the DBTAC must be sufficiently familiar with not only the ADA, but also the Fair Housing Act. Thus to respond directly or to refer the inquirer to an expert source of technical assistance, the DBTACs must be knowledgeable about a wide array of disability-related or disability rights laws.

Priority 2: We will establish a Regional DBTAC in each of the Department of Education 10 regions to facilitate implementation of the ADA. Each center must:

(1) Provide technical assistance and training and disseminate information to individuals and entities with responsibilities and rights under the ADA on the ADA's requirements as well as developments in case law, policy, and implementation;

(2) Increase the capacity of organizations, at the State and local level, including CILs, to provide technical assistance and training on, disseminate information on, and promote awareness of the ADA;

(3) Promote awareness of the ADA and the availability of services provided by the DBTACs, other NIDRR-sponsored ADA grantees, and other Federal information sources on the ADA;

(4) Provide technical assistance and training and disseminate information on legal obligations of educational entities to provide accessible IT to students and employees;

(5) Provide technical assistance to educational entities to enable them to conduct self-evaluations on the accessibility of their IT;

(6) Provide technical assistance, either directly or through referral, on how to make existing IT accessible and ensure that new IT acquisitions are accessible;

(7) Promote ''best practices'' by encouraging educational entities to purchase IT consistent with the standards issued by the Access Board under Section 508 or universal design principles, regardless of whether they have a legal obligation to do so;

(8) Provide information to independent living centers, Parent Training Information Centers, and the Regional Resource Centers on accessible education-based IT; and

(9) Form regional partnerships among Assistive Technology Act grantees, RERCs, Office of Special Education Programs' technology grantees, and other pertinent educational organizations and agencies to guide, coordinate, and if appropriate, carry out technical assistance activities in each region.

In carrying out these activities each DBTAC must:

- Involve individuals with disabilities, parents or other family members of individuals with disabilities, in all phases of the design and operation of the DBTAC to the maximum extent possible;
- Be knowledgeable about a wide array of disability-related or disability rights laws including, but not limited to, sections 504 and 508 of the Rehabilitation Act, the Individuals with Disabilities Education Act, the Air Carriers Access Act, section 255 of the Telecommunications Act, section 188 of the Workforce Investment Act, the Fair Housing Act, the Family and Medical Leave Act, the AT Act, and workers' compensation laws;
- Coordinate its activities with the National Center on Accessible Education-based IT, and Federal agencies including, but not limited to, the Department of Justice, the Equal Employment Opportunity Commission, the Department of Transportation, the Federal Communications Commission, the Access Board, the Department of Education's Office for Civil Rights, the President's Committee on Employment of Persons with Disabilities, the National Council on Disability, and other offices within the Department of Education including the Rehabilitation Services Administration, and the Office of Special Education Programs;
- Provide performance accountability data on a monthly and annual basis as requested by NIDRR;
- Distribute services and resources equitably—taking into account population and size—among each State in its region;
- Address the needs of non-English speaking populations; and
- Include in their target audience for activities (4), (5), (6) and (7): elementary and secondary institutions, and postsecondary educational entities including, but not limited to, institutions of higher learning, proprietary schools (particularly those offering IT training), and adult education programs.

In carrying out its evaluation activities, a DBTAC may maintain the ADA Impact Measurement System.

Additional Selection Criterion for the DBTACs and the National Center on Accessible Education-Based IT Priorities

We will use the selection criteria in 34 CFR 350.54 to evaluate applications under this program. In evaluating applications for the DBTACs and the National Center on Accessible Education-based IT and, we will also use the following factor under the project staff criterion. In determining the quality of the project staff, we will consider the extent to which key personnel have expert knowledge about state-of-the-art IT to conduct all proposed activities.

Disability and Rehabilitation Research Project and Centers Program

The purpose of the DRRP program is to plan and conduct research, demonstration projects, training, and related activities to:

(a) Develop methods, procedures, and rehabilitation technology that maximizes the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities; and

(b) Improve the effectiveness of services authorized under the Act.

Additional Selection Criterion

We will use the selection criteria in 34 CFR 350.54 to evaluate applications under these programs. The maximum score for all the criteria is 100 points; however, we will also use the following criterion so that up to an additional ten points may be earned by an applicant for a total possible score of 110 points.

Up to ten (10) points based on the extent to which an application includes effective strategies for employing and advancing in employment qualified individuals with disabilities in projects awarded under this absolute priority. In determining the effectiveness of those strategies, we will consider the applicant's prior success, as described in the application, in employing and advancing in employment qualified individuals with disabilities.

Thus, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for these priorities. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Applicable Program Regulations: 34 CFR part 350.

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(Catalog of Federal Domestic Assistance Numbers 84.133D, Disability Rehabilitation Research Project)

Program Authority: 29 U.S.C. 762(g) and 764(b)(4).

Dated: December 26, 2000.

Curtis L. Richards,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

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Federal Register

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Part VIII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1271

Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 97N–484P]

Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations to require manufacturers to follow current good tissue practice, which includes methods used in, and the facilities and controls used for, the manufacture of human cellular and tissue-based products; recordkeeping; and the establishment of a quality program. The agency is also proposing new regulations pertaining to labeling, reporting, inspections, and enforcement that will apply to manufacturers of those human cellular and tissue-based products that the agency is proposing to regulate solely under the authority of the Public Health Service Act (PHS Act) and not as biological drugs or as devices. The agency's actions are intended to improve protection of the public health while permitting significant innovation and keeping regulatory burden to a minimum.

DATES: Submit written comments on the proposed rule by May 8, 2001. Submit written comments on the information collection provisions by February 7, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is in the process of establishing a comprehensive new system for regulating human cellular and tissue-based products. In an earlier related rulemaking, the agency proposed to define a human cellular or tissue-based product as a ''product containing or consisting of human cells or tissues that is intended for implantation, transplantation, infusion, or transfer into a human recipient * * *'' (''Suitability Determination for Donors of Human Cellular and Tissue-based Products,'' proposed rule (64 FR 52696, September 30, 1999), hereinafter ''donor-suitability proposed rule''). ''Transfer'' is a term used with respect to reproductive cells and tissues, and has also been defined in another related proposal (''Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-based Products,'' proposed rule (63 FR 26744 at 26754, May 14, 1998), hereinafter ''registration proposed rule'').

Examples of human cellular and tissue-based products include cadaveric ligaments, skin, bone, dura mater, heart valves, corneas, blood hematopoietic stem cells, manipulated autologous chondrocytes, and spermatozoa. Certain exclusions from the definition of human cellular and tissue-based products may be applicable and have been discussed in earlier rulemakings (registration proposed rule, 63 FR 26744 at 26748; donor-suitability proposed rule, 64 FR 52696 at 52700).

The regulations now being proposed would require all human cellular and tissue-based products to be manufactured in compliance with current good tissue practice (CGTP). The proposal also contains provisions relating to establishment inspection and enforcement, as well as certain labeling and reporting requirements, which would be applicable to those human cellular and tissue-based products that the agency is proposing to regulate solely under the authority of section 361 of the PHS Act and not as biological drugs or devices.

The agency also requests consultation from the States on any preemption issues raised by the proposed CGTP rule, specifically with regard to: (1) the need for CGTP requirements to prevent communicable disease transmission through human cellular and tissue-based products; (2) alternatives that would limit the scope of such national requirements or otherwise preserve State prerogatives and authority; and (3) any other issues raised by this proposed rule that could affect State laws and authorities.

A. Background

In February 1997, FDA proposed a new, comprehensive approach to the regulation of human cellular and tissue-based products. The agency announced its regulatory plans in two documents: ''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 proposed rules that would implement aspects of the proposed approach. On May 14, 1998, the agency proposed regulations that would create a new, unified system for registering establishments that manufacture human cellular and tissue-based products and for listing their products (registration proposed rule at 63 FR 26744). On September 30, 1999, FDA proposed regulations that would require most cell and tissue donors to be tested and screened for relevant communicable diseases (donor-suitability proposed rule at 64 FR 52696 at 52719).

With the present rulemaking, the agency is completing the set of proposals that would implement the new regulatory scheme. 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. Thus, the agency is now proposing to require that establishments that manufacture human cellular or tissue-based products 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 regulations would be contained in title 21 CFR in new part 1271, along with provisions relating to establishment registration and donor suitability that have been proposed previously. Subpart A of part 1271 would set forth scope and purpose as well as definitions. Subpart B of part 1271 would contain registration procedures. Subpart C of part 1271 would set forth provisions for the screening and testing of donors in order to determine their suitability. Subpart D of part 1271 would contain the provisions on CGTP now being proposed. Subpart E of part 1271 would contain certain labeling and reporting requirements and subpart F of part 1271

would contain the inspection and enforcement provisions applicable to those human cellular and tissue-based products regulated solely under the authority of section 361 of the PHS Act. The agency proposes to revoke part 1270 (21 CFR part 1270), which will be superseded by new part 1271.

B. The Tiered, Risk-Based Regulatory Approach

The proposed approach document set out a tiered regulatory scheme, under which human cellular and tissue-based products would be subject to an appropriate level of regulation based on the degree of risk and the necessity for FDA review. Certain human cellular and tissue-based products (e.g., tissues that are more than minimally manipulated) would be regulated as biological drugs or medical devices under the Federal Food, Drug, and Cosmetic Act (the act) and/or section 351 of the PHS Act (42 U.S.C. 262), and thus would be subject to premarket review procedures, among other requirements. FDA is proposing to regulate other human cellular and tissue-based products solely under the authority of section 361 of the PHS Act (42 U.S.C. 264), which authorizes the agency to issue regulations to prevent the introduction, transmission, or spread of communicable diseases. (These products are referred to in this document as ''361 products.'')

The proposed tissue regulations would apply to a wide range of human cells and tissues. To simplify terminology, the proposed regulations refer generally to all human cells and tissues, including reproductive tissue, as ''products,'' and refer to persons who recover, screen, test, process, store, label, package, or distribute human cellular and tissue-based products as ''manufacturers.'' The term ''product'' is a term of art coined under Section 351 of the PHS Act, i.e., ''biological product,'' while the term ''manufacturer'' is used in FDA's current regulations that affect biological products, drugs, and devices. However, Section 361 of the PHS Act, which gives FDA the authority to make and enforce regulations to prevent the spread of communicable disease, does not require use of the term ''product'' to define its scope. The agency has received comments to the first two proposed rules to implement the proposed approach objecting to the use of the terms ''product'' and ''manufacturer'' as applied to human cells and tissues. In finalizing these rules, the agency will consider whether alternative terminology to describe the scope of the regulations should be used.

FDA anticipates that determining the regulatory process for certain cellular and tissue-based products may be complicated. To help answer questions about how a particular cellular or tissue-based product will be regulated, the agency developed the Tissue Reference Group (TRG). The TRG is composed of: (1) Three representatives from the Center for Biologics Evaluation and Research (CBER); (2) three representatives from the Center for Devices and Radiological Health (CDRH); (3) the product jurisdictional officer from each Center; and (4) a liaison from the agency's Office of the Chief Mediator and Ombudsman (OCMO), a nonvoting member. Other FDA staff attend the TRG meetings as needed to discuss issues related to products in their area of expertise. The TRG provides a single reference point and makes recommendations to the center directors regarding product jurisdiction of specific tissue.

In addition, FDA recognizes that further public discussion of how the proposed tissue regulations would be applied to certain categories of human cells and tissues may be warranted due to the complexity or sensitivity of the issues. For example, the agency held a public meeting to discuss how proposed definitions for ''minimally manipulated'' and ''homologous use'' should be applied to human bone allograft products on August 2, 2000. FDA intends to provide further opportunities for public discussion of how the regulatory approach should be applied to reproductive cells and tissue. FDA anticipates that there may be additional needs for discussion through public meetings, public hearings, or guidance as the agency implements the new regulations. The regulatory categories applicable to human cellular and tissue-based products are discussed in greater detail in the registration and donor-suitability proposed rules (63 FR 26744 at 26746; 64 FR 52696 at 52698).

Under the regulatory scheme being proposed at part 1271, all human cellular and tissue-based products, regardless of the regulatory category in which they belong, would be subject to certain core requirements designed to address concerns common to all such products. (These core requirements will cover registration procedures, donor testing and screening, and CGTP, and will be in subparts B, C, and D of part 1271.) Because of their nature as derivatives of the human body, all human cellular and tissue-based products pose a potential risk of transmitting communicable diseases. Thus, the donor-suitability proposed rule would require that most cell and tissue donors be tested and screened for evidence of relevant communicable-disease infection. Similarly, the CGTP regulations now being proposed are designed to prevent the introduction, transmission, and spread of communicable diseases. For example, compliance with CGTP would require such precautions as cleaning of facilities and equipment, storage procedures designed to prevent product mix-ups, and controls over processing to prevent product contamination and impairment to function or integrity.

Those human cellular or tissue-based products regulated solely under the authority of section 361 of the PHS Act would be subject only to the requirements contained in part 1271. In contrast, human cellular or tissue-based products regulated as devices or biological drugs would be subject not only to the core requirements contained in subparts B, C, and D of part 1271, but also to other applicable statutory and regulatory requirements.

C. Legal Authority

FDA is proposing to issue these new regulations under the authority of section 361 of the PHS Act. Under section 361 of the PHS Act, 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. (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for delegation of section 361of the PHS Act authority from the Surgeon General to the Secretary, Health and Human Services; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) Intrastate transactions may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).)

Certain diseases, such as those caused by the human immunodeficiency virus (HIV) and the hepatitis B and C viruses, may be transmitted through the implantation, transplantation, infusion, or transfer of human cellular or tissue-based products derived from infected donors. The agency has, in an earlier rulemaking, proposed that most cell and tissue donors be screened and tested for these and other relevant communicable diseases (donor-suitability proposed rule, 64 FR 52696 at 52720). However, donor screening and testing, although crucial, are not sufficient to prevent the transmission of disease by human cellular and tissue-based products. Rather, each step in the manufacturing process needs to be controlled. Errors in labeling, mix-ups of testing records, failure to adequately clean work areas,

and faulty packaging are all examples of improper practices that could lead to a product capable of transmitting disease to its recipient. Similarly, as noted in the proposed approach document, improper handling of a human cellular or tissue-based product can lead to bacterial contamination of the product or to cross-contamination between products.

In addition to the direct transmission of communicable disease agents by human cellular and tissue-based products to their recipients, the agency is also concerned about the spread of communicable disease through the use of products whose function or integrity have been impaired. When a product does not work in a patient because it has not been manufactured properly, the risk of introducing, transmitting, or spreading a communicable disease is increased each time a procedure is repeated for at least two reasons: (1) Despite the best controls, there is a risk, albeit smaller than without controls, of communicable disease transmission, and (2) a procedure for transfer or transplant can carry an independent risk of communicable disease transmission. For example, use of a product whose function or integrity may have been compromised could create a circumstance that increases a patient's need for an additional transfer or transplant attempt. A repeat surgical procedure necessitated by the damaged product would further expose the patient to the additional communicable disease risks inherent in any such procedure. Moreover, a patient in a weakened state from the first unsuccessful procedure is at greater risk of contracting a communicable disease by experiencing a repeat procedure. Therefore, the agency considers that requirements aimed at maintaining product function and integrity are necessary, and thus may be issued under section 361 of the PHS Act.

The proposed CGTP regulations would govern the methods used in, and the facilities and controls used for, the manufacture of human cellular and tissue-based products. CGTP requirements are a fundamental component of FDA's risk-based approach to regulating human cellular and tissue-based products. Products that the agency is proposing to regulate solely under section 361 of the PHS Act and proposed part 1271, would be subject to less rigorous agency oversight than products also regulated under the act and/or section 351 of the PHS Act. By requiring that 361 products be manufactured in compliance with CGTP, in combination with the other proposed requirements in part 1271, the agency can be assured that 361 products are subject to sufficient regulatory controls to protect the public health.

FDA is proposing that the CGTP regulations would supplement, but not supersede, the current good manufacturing practice (CGMP) and quality system (QS) regulations applicable to drugs and devices in parts 210, 211, and 820 (21 CFR parts 210, 211, and 820). Under the proposed rule, human cellular and tissue-based products regulated as biological drugs under the act and section 351 of the PHS Act, or as devices under the act, would have to be manufactured in accordance with CGTP, in addition to existing requirements. Thus, in keeping with the plan outlined in the proposed approach document, those products regulated as biological drugs or devices would be subject to more comprehensive regulation of manufacturing than the 361 products.

In the donor-suitability proposed rule, the agency proposed to amend the existing CGMP regulations for drugs and the QS requirements for devices to incorporate the testing and screening provisions of proposed part 1271, subpart C. At that time, in order to obviate the need for further revisions, the agency also proposed to amend those sections to incorporate the current good tissue practice procedures of proposed part 1271 subpart D. In amending the CGMP and QS regulations, FDA is relying both on the authority provided by section 361 of the PHS Act to make regulations to prevent the spread of communicable disease, and on its authority under the act to issue CGMP regulations (section 301(a)(2)(B) and (h) of the act) (21 U.S.C. 351(a)(2)(B) and (h)), section 520(f)(1) of the act (360j(f)(1)); section 701 of the act (21 U.S.C. 371)).

Under proposed 21 CFR 210.1(c), the manufacturer of a human cellular or tissue-based product regulated as a drug or biological drug would be required to comply with the CGTP procedures in part 1271, subpart D (donor suitability proposed rule, (64 FR 52696 at 52699 and 52719)). Likewise, under proposed 21 CFR 820.1, the manufacturer of a human cellular or tissue-based product regulated as a device would be required to comply with the same procedures (donor suitability proposed rule (64 FR 52696 at 52699 and 52719)). If the manufacturer failed to follow the CGMP requirements, including the good tissue practice procedures in part 1271, the product would be adulterated under section 501(a)(2)(B) of the act.

FDA is also relying on its authority under section 361 of the PHS Act to propose several reporting, labeling, inspection, and enforcement provisions. Because products regulated under the act and/or section 351 of the PHS Act, are subject to similar regulation requirements, these provisions would apply only to 361 products. Proposed subpart E of part 1271 contains regulations on reporting and labeling pertaining to 361 products and is discussed in section III of this document. Proposed subpart F of part 1271 contains inspection and enforcement provisions also applicable only to 361 products; the relevant discussion appears in section IV of this document.

II. Summary of the Proposed CGTP Regulations

The regulations being proposed would require manufacturers of human cellular and tissue-based products to follow CGTP, which includes proper handling, processing, storage, and labeling of human cellular and tissue-based products, recordkeeping, and the establishment of a quality program. The proposed CGTP regulations are designed to address issues common to all human cellular and tissue-based products, and so are intentionally broad in scope. The agency anticipates that, as it implements the new regulations, there may be additional need for discussion, through public meetings, public hearings, or guidance, of how these general regulations would apply to specific types of products. In addition, there may be specific elements of these proposed requirements that some readers may not consider appropriate to general application. The agency welcomes comments that will assist it in achieving the proper balance between generality and specificity in these regulations.

A. General Provisions (Proposed §§ 1271.150 and 1271.155)

Proposed § 1271.150 contains general provisions intended to aid in the interpretation of the requirements contained in subparts C and D of part 1271. Proposed § 1271.155 sets out the procedures for obtaining an exemption or variance from one or more of these requirements.

1. Current Good Tissue Practice (Proposed § 1271.150(a))

Proposed § 1271.150(a) states that CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of human cellular and tissue-based products. CGTP requirements are intended to prevent the introduction, transmission, and spread of communicable disease through the use of human cellular and tissue-based products by helping to

ensure that: (1) The products do not contain relevant communicable disease agents; (2) they are not contaminated during the manufacturing process; and (3) the function and integrity of the products are not impaired through improper manufacturing, all of which could lead to circumstances that increase the risk of communicable disease transmission. ''Manufacture'' as defined in the registration proposed rule, includes, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cellular or tissue-based product, and the screening and testing of a cell or tissue donor (proposed § 1271.3(f), 63 FR 26744 at 26754.) The definition of ''human cellular or tissue-based product'' as revised in the donor suitability proposed rule, is intended to cover such products at all stages of their manufacture, from recovery through distribution (see proposed § 1271.3(e) (64 FR 52696 at 52719). For a human cellular or tissue-based product to be manufactured properly, CGTP must be followed in each step of the manufacturing process.

The word ''current'' is included in the term ''current good tissue practice'' because the agency recognizes that appropriate practices may change over time, as research is conducted and new manufacturing methods are developed. These regulations are not intended to require that practices considered current at the time of issuance of the final regulations be maintained indefinitely; instead, the obligation on an establishment is to maintain up-to-date practices over time. Recognizing that improved manufacturing techniques may be developed, the agency has generally refrained in these proposed regulations from requiring specific procedures, such as particular processing methods or storage temperatures. Instead, the proposed regulations set out general objectives. This approach not only allows for new developments, but also affords establishments flexibility in developing procedures that are both appropriate to their particular operations and that comply with the regulations.

The proposed requirements are based on current good industry practice and are intended to address what the agency considers important minimum criteria for the manufacture of these products. In developing these regulations, the agency has reviewed several sets of industry standards, including those issued by the American Association of Tissue Banks (AATB) and by the Eye Bank Association of America (EBAA). The agency expects that some establishments will need to make only small changes in their operations to achieve compliance. Other establishments may find that complying with the new requirements entails revising certain procedures and recordkeeping practices, but few operational changes. Another group of establishments—for example, those that have not previously been subject to regulation and that do not belong to any standard-setting or accrediting organization—may need to revise their procedures more completely, in order to bring them into compliance with these regulations and industry practice.

Proposed § 1271.150(a) states that CGTP requirements are set forth in subparts C and D of part 1271. The CGTP provisions specifically governing donor suitability, including donor testing and screening, are set out separately in subpart C of part 1271. The agency notes that § 1271.90 contains exceptions from required testing and screening for two types of human cellular and tissue-based product: Banked cells and tissues for autologous use, and reproductive cells or tissue donated by a sexually-intimate partner of the recipient for reproductive use (64 FR 52696 at 52723). (Donor testing and screening are recommended, however.) The agency specifically notes that the exceptions in § 1271.90 apply only to subpart C of part 1271 and do not extend to the provisions of subpart D of part 1271. Because the safety concerns addressed by the proposed CGTP requirements apply to all human cellular and tissue-based products, no exceptions are being proposed for any particular category of product. Thus, banked cells and tissues for autologous use, and reproductive cells or tissue donated by a sexually-intimate partner of the recipient for reproductive use, would be subject to the CGTP requirements in subpart D of part 1271.

2. Compliance With Applicable Requirements (Proposed § 1271.150(b))

FDA recognizes that several establishments may be involved in the manufacture of a single human cellular or tissue-based product. For example, one establishment may recover tissue from a cadaver, another establishment may make the donor-suitability determination, a third may process the tissue, and a fourth may distribute the product. The agency has taken care, in designing these proposed regulations, to reflect the fact that manufacturing roles might be divided up in a variety of possible ways. Thus, under proposed § 1271.150(b), an establishment that engages in only some operations subject to the regulations in subparts C and D of part 1271 need only comply with those requirements applicable to the operations in which it engages. Under § 1271.150(b), an establishment that does not process cells or tissue would not be obligated to establish and maintain process controls under proposed § 1271.220. However, an establishment that engages another establishment, under a contract, agreement, or other arrangement, to perform any step in the manufacturing process, would be responsible for ensuring that the work is performed in compliance with the requirements in subparts C and D of part 1271. One method of accomplishing this might be by performing periodic audits.

Given that the steps in manufacturing a single human cellular or tissue-based product may be carried out by several establishments, FDA considers it essential that additional safeguards be established to ensure compliance with regulatory requirements throughout the manufacturing process. The agency has considered various ways of allocating regulatory responsibilities among the establishments involved in manufacturing a human cellular or tissue-based product. The agency seeks to permit establishments to maintain flexibility in sharing manufacturing responsibilities, while ensuring that products made available for release maintain their function and integrity, are not contaminated, and do not contain communicable disease agents.

The agency first considered assigning overall responsibility for ensuring that a human cellular and tissue-based product is manufactured in compliance with all applicable regulations to the establishment that determines donor suitability. However, the agency recognized that the role this establishment plays in the manufacture of a human cellular or tissue-based product occurs early in the sequence of manufacturing events. As a practical matter, the establishment that determines donor suitability might not be able to ensure that later manufacturing steps, such as processing and labeling, are performed in compliance with the regulations. A more pragmatic approach would be to assign responsibility to the establishment that makes a product available for distribution.

Another option would be to permit the establishments engaged in the manufacturing process to decide among themselves which party bears ultimate responsibility for the product. However, the agency is concerned that, under this approach, there would be occasions when no establishment would step forward as the one ultimately responsible, and that as a consequence

compliance with certain requirements might not be accomplished. As a result, products might be released that pose a risk of transmitting communicable disease or otherwise increasing the risk of disease transmission. For the same reasons, FDA has rejected the idea that designating a responsible establishment is unnecessary.

The agency has also considered a ''cascading'' set of responsibilities. Under this approach, 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.

After considering the unique nature of the cell and tissue industry, and each of the above options, the agency has tentatively concluded that the best approach is to assign ultimate responsibility for the product to the establishment that is responsible for making the product available for distribution. This is consistent with the proposed approach document, which stated that ''[t]he establishment or person responsible for determining suitability of release of cells or tissues would be responsible for ensuring that required screening and testing had been performed prior to final release of the material.'' Thus, proposed § 1271.150(b) states that the establishment that determines that a product meets release criteria and makes the product available for distribution, whether or not that establishment is the actual distributor, is responsible for ensuring that the product has been manufactured in compliance with the requirements of subpart C and D of part 1271 and any other applicable requirements.

The agency specifically requests comments on the allocation of overall manufacturing responsibility. Examples of industry arrangements currently in existence would be particularly useful to the agency in evaluating the comments on these proposed regulations.

3. Compliance With Parts 210, 211, and 820

The proposed CGTP regulations are similar to the CGMP requirements applicable to drugs and the QS requirements for devices. However, the CGMP and QS regulations do not contain provisions specifically intended to prevent the spread of communicable disease. In contrast, the purpose of the proposed CGTP regulations is limited to preventing circumstances that increase the risk of introduction, transmission, and spread of communicable disease; the proposed regulations are therefore less extensive in scope than the CGMP and QS regulations.

Proposed § 1271.150(c) states that, with respect to human cellular and tissue-based products regulated as biological drugs or as devices, the proposed CGTP procedures will supplement, not supersede, the CGMP and QS requirements. Proposed § 1271.150(c) states that, in the event that it is impossible to comply with all applicable regulations, the regulations specifically applicable to the biological drug or device in question shall supersede the more general.

4. ''Where Appropriate''

Several of the requirements contained in part 1271, subpart D, are qualified by the term ''where appropriate,'' which as explained in proposed § 1271.150(d), are considered to be appropriate, and must be followed, unless an establishment can justify otherwise, and maintains documentation of that justification. Under proposed § 1271.150(d), a requirement is ''appropriate'' if nonimplementation could reasonably be expected to result in the: (1) Product's not meeting its specified requirements related to preventing the introduction, transmission, and spread of communicable disease agents and diseases; or (2) manufacturer's inability to carry out any necessary corrective action.

5. Exemptions and Alternatives (Proposed § 1271.155)

FDA recognizes the possibility that, as technology and scientific knowledge advance, new methods may be developed that could be used in the manufacture of human cellular and tissue-based products, or other unanticipated circumstances may arise that warrant a departure from an approach detailed in the regulations. Some of these technical developments may not be consistent with the terms of the donor-suitability and CGTP regulations, although the purpose of those regulations might be satisfied. In order to provide establishments with flexibility, and to ensure that the agency may respond appropriately to improved technologies and increased scientific knowledge, the agency proposes that establishments may apply for exemptions or alternatives from the regulatory requirements contained in subparts C and D of part 1271.

Proposed § 1271.155 sets out the procedures for obtaining an exemption or alternative from a requirement in subpart C of part 1271, pertaining to donor suitability, or in subpart D of part 1271, pertaining to CGTP. Under proposed § 1271.155, an establishment could demonstrate to the agency that it should be exempted from an otherwise applicable regulatory requirement or permitted to satisfy the purpose of the requirement in an alternative manner. A request for an exemption or alternative would need to be accompanied by supporting documentation, including all relevant valid scientific data. Requests would be made in writing or electronically, except that in limited circumstances (e.g., emergencies) a request might be made and granted orally, with a written request and acknowledgment of approval to follow.

Under proposed § 1271.155(c), the Director of the Center for Biologics Evaluation and Research (CBER) could grant an exemption or alternative if he or she found that doing so would be consistent with the goals of preventing circumstances that increase the risk of the introduction, transmission, and spread of communicable disease. In addition, an exemption or alternative would be conditioned on a finding by the Director that the information submitted justified an exemption or that the proposed alternative satisfied the purpose of the requirement. An establishment that requested an exemption or alternative could not begin operating under its terms until the exemption or alternative had been granted. Some exemptions or alternatives might have expiration dates, in which case an extension could be requested. An establishment operating under the terms of an exemption or alternative would be required to maintain documentation that the exemption or alternative had been granted, and of the date on which the establishment began operating under the terms of the exemption or alternative.

B. Definitions (Proposed § 1271.3)

Definitions pertinent to part 1271 will be contained in subpart A, in § 1271.3. In the registration proposed rule, FDA set out defined terms in paragraphs (a) through (h) of § 1271.3. In the donor-suitability proposed rule, further definitions were proposed, to be contained in § 1271.3(i) through (ee), and the proposed definition of human cellular or tissue-based product in paragraph (e) was revised.

Now, the agency is proposing new paragraphs (ff) through (tt) in § 1271.3. These new definitions are discussed below, when the requirements to which the defined terms relate are discussed.

C. Quality Program (Proposed § 1271.160)

Any establishment that manufactures human cellular or tissue-based products

needs to have in place a method of ensuring that its manufacturing processes are performed properly and in compliance with applicable regulations. For devices, such a program is called a ''quality system'' (§ 820.1 *et seq.*). In these regulations, FDA is proposing to use ''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. FDA proposes to define ''quality program'' in § 1271.3(oo) as ''an organization's comprehensive system for manufacturing and tracking human cellular and tissue-based products. This program includes preventing, detecting, and correcting deficiencies that may lead to circumstances that increase the risk of the introduction, transmission, or spread of communicable disease.''

Proposed § 1271.160 would require an establishment that performs any step in the manufacture of human cellular and tissue-based products to establish and maintain a quality program that is appropriate for the specific human cellular and tissue-based products manufactured and the manufacturing steps performed and that meets the requirements of this part. With proposed § 1271.160, FDA intends to require that a quality program perform certain basic functions, but also intends to provide each establishment with flexibility to devise a program appropriate to its particular activities and characteristics. Thus, FDA expects that quality programs may differ from establishment to establishment, depending on the size of the establishment and the type of manufacturing performed, among other factors. A smaller company that performs limited manufacturing steps might have a less complex quality program than a larger establishment that processes a variety of products.

Some establishments may currently have in place quality programs that would meet the requirements of proposed § 1271.160. An establishment that manufactures human cellular and tissue-based products regulated as devices would likely find it unnecessary to make major changes to its quality system established in compliance with § 820.5 in order to comply with proposed § 1271.160. Such an establishment would not need to maintain both a QS and a separate quality program.

The functions of a quality program, as listed in proposed § 1271.160(b), include but are not limited to: (1) Ensuring that required procedures are established and maintained; (2) ensuring the appropriate analysis and sharing of information that could affect the integrity and function of a human cellular or tissue-based product, possible contamination of the product, or the potential transmission of communicable disease by the product; (3) ensuring that appropriate corrective actions are taken and documented; (4) ensuring the proper training and education of personnel; (5) establishing and maintaining appropriate monitoring systems; (6) establishing and maintaining a system for maintaining records; (7) investigating and documenting product deviations and making certain required reports; and (8) conducting evaluations, investigations, audits, and other actions necessary to ensure compliance with the regulations.

Proposed § 1271.160(b)(2) would specifically require procedures to be established for sharing and receiving information that could affect the integrity and function of a human cellular or tissue-based product, the possible contamination of the product, or the potential transmission of communicable disease by the product. This would include information on testing or screening results that could make a donor unsuitable; such information would need to be shared with other establishments that are known to have recovered cells or tissue from the same donor. An establishment would also need procedures in place in order to respond appropriately (through investigation, evaluation, possible recall, reporting, etc.) if it received any such information from another establishment.

Proposed § 1271.160(b)(7) would require establishments to investigate and document all product deviations in manufacturing. The term ''product deviation'' is defined in proposed § 1271.3(kk) as ''an event that represents a deviation from current good tissue practice, 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 a human cellular or tissue-based product to a recipient, may lead to product contamination, or may adversely affect the function or integrity of the product.'' Investigation would be required to include a review and evaluation of the product deviation in manufacturing, the efforts made to determine the cause, and the implementation of corrective action designed to address the event and prevent its recurrence.

Certain product deviations in manufacturing would be required to be reported. The proposed requirement, applicable to distributed 361 products, for reporting product deviations in manufacturing that could lead to adverse reactions is discussed below in section III of this document. Certain product variations, referred to currently as errors and accidents, involving human cellular and tissue-based products regulated as biological drugs are required to be reported under 21 CFR 600.14 (currently undergoing revisions; see 62 FR 49642, September 23, 1997). In addition, each establishment would be required to perform a periodic review and analysis of all investigations of product deviations in manufacturing, at least once each year, for the purpose of identifying trends and adopting appropriate corrective and preventive measures. Section 1271.160(b)(7) specifies that this analysis shall be available for review upon inspection and for submission to FDA upon request.

Under proposed § 1271.160(c), one or more designated persons shall have authority over the quality program, and this person shall report to management at least once a year on the performance of the quality program. However, more frequent reports may be necessary in order to keep management informed of the status of the program.

Audits are an important component of a quality program. Under proposed § 1271.160(d), a comprehensive quality audit of all activities would be required at least once a year. FDA proposes to define ''quality audit'' in proposed § 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.'' In addition to the annual quality audit, special audits would be performed as necessary to ensure that quality program objectives are achieved.

Proposed § 1271.160(e) covers the use of computers or automated data processing systems used as part of the quality program, as part of manufacturing, or for maintaining manufacturing data or records. An establishment using such a computer or automated system would be required to validate the computer software for its intended use according to an established protocol, as well as all software changes. Validation and results would be required to be documented. The agency proposes to define

''validation'' in proposed § 1271.3(rr) as ''confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled * * *''.

D. Organization and Personnel (Proposed § 1271.170)

Proposed § 1271.170 sets out general requirements for the organization and personnel of establishments that manufacture human cellular and tissue-based products. Under this section, each establishment would be required to maintain an adequate organizational structure and sufficient personnel to ensure that the requirements of part 1271 are met. Moreover, an establishment would need to have sufficient personnel with the necessary education and experience, or combination thereof, to assure competent performance of their assigned functions.

Under proposed § 1271.170, personnel would only be permitted to perform those activities for which they are qualified. Training of personnel to perform their assigned responsibilities adequately would be required, as would any necessary retraining. Because of the particular risks addressed by the requirements of part 1271, the agency is proposing to require that personnel be educated about possible consequences of improperly performing their duties; e.g., the risk that an improperly handled product could cause harm to the product's recipient, by transmitting a communicable disease or by failing to function adequately. A record of the education, experience, training, and retraining would need to be maintained for all personnel.

E. Procedures (Proposed § 1271.180)

Under proposed § 1271.180, each establishment would be required to establish and maintain procedures for all significant steps that it performs in the manufacture of human cellular and tissue-based products. The agency is proposing to define ''establish and maintain'' in § 1271.3(ll) as ''define, document (in writing or electronically), and implement, then follow, review, and as needed, revise on an ongoing basis.'' FDA intends, by using the phrase ''establish and maintain'' in these regulations, to indicate that, once established, procedures must be followed on an ongoing basis. Because established procedures would, by definition, be documented in writing or electronically, the agency is proposing to use the term ''procedures'' as opposed to ''written procedures.''

Procedures required under proposed § 1271.180, and those specifically required elsewhere in subpart D of part 1271, would be required to be designed to prevent circumstances that increase the risk of the introduction, transmission, and spread of communicable diseases through the use of human cellular and tissue-based products by ensuring that: (1) The products do not contain relevant communicable disease agents; (2) the products do not become contaminated during manufacturing; and (3) the function and integrity of the products are not impaired through improper manufacturing. Procedures must be designed to ensure compliance with the requirements of part 1271.

The recovery of cells or tissue is an example of an especially significant step in the manufacture of a human cellular or tissue-based product, for which procedures would have to be established. Under the terms of proposed § 1271.180, such procedures would need to include the use of procurement techniques designed to prevent the transmission of communicable disease agents and diseases by the product. In addition, procedures for recovery would have to be designed to ensure that the function and integrity of the procured cells or tissue are maintained during and after procurement.

All procedures shall be reviewed and approved by a responsible person prior to implementation. At least once in a 12-month period, all procedures would be required to be reviewed and, if necessary, revised; such review would need to be documented. Procedures must be readily available to personnel in the area where relevant operations are performed, unless this would be impractical. Any deviation from a procedure must be authorized by a responsible person, recorded, and justified.

FDA is not prescribing the contents of particular procedures, but is allowing establishments to develop procedures that suit their particular operations. Alternatively, under proposed § 1271.180, an establishment could adopt current standard procedures, e.g., those in a technical manual prepared by another organization, so long as the procedures are consistent with the requirements of part 1271, at least as stringent as those requirements, and appropriate for the establishment's operations.

Any procedure that becomes obsolete would be required to be archived for at least 10 years. Since some tissues have long expiration dates, they can be transplanted many years after they were recovered or processed. Should an adverse reaction occur after transplantation, it would be important to know the procedures under which the tissue was recovered or processed, especially if those procedures differ from the ones currently in place.

F. Facilities, Environmental Control and Monitoring, Equipment, and Supplies and Reagents

1. Facilities (Proposed § 1271.190)

Under proposed § 1271.190, any facility used in the manufacture of human cellular or tissue-based products must be of suitable size, construction, and location to facilitate cleaning, relevant maintenance, and proper operations. A facility that, for whatever reason, cannot be adequately cleaned is not appropriate for use in the manufacture of human cellular and tissue-based products, because of the potential risk of product contamination. ''Relevant maintenance'' refers to those actions that, if not taken, could lead to potentially adverse effects on product integrity or function, or to the accidental exposure of human cellular and tissue-based products to communicable disease agents, or to contamination or cross-contamination with such agents. Finally, any operation undertaken by a manufacturing establishment needs to be performed in a facility in which the operation can be performed correctly. For example, although not specifically required to do so by these regulations, an establishment may need to establish gowning procedures for its employees, in order that their functions be performed properly. Such an establishment would need to provide employees with a dressing room and gowning area.

Proposed § 1271.190 would also require that a facility be maintained in a good state of repair. Broken windows, peeling paint, uneven flooring, and improper electrical wiring are all examples of maintenance problems that could lead to product contamination or impairment of product function or integrity. In addition, adequate lighting, ventilation, plumbing, drainage, and washing and toilet facilities would all be required.

Proposed § 1271.190(b) sets out requirements for the location of operations within a facility used in the manufacture of human cellular or tissue-based products. Such a facility would need to be divided into separate or defined areas of adequate size for each operation that takes place in the facility. As an alternative, however, other control systems could be established and maintained to prevent improper labeling, mix-ups, contamination, cross-contamination,

and accidental exposure of human cellular and tissue-based products to communicable disease agents. Examples of different types of operations that an establishment might perform, and which would need to be conducted either in separate locations or subject to other controls, include: (1) Receipt, identification, and storage of containers, labels, supplies, and reagents; (2) processing, including laboratory functions; (3) storage of human cellular and tissue-based products, both before and after release from quarantine; (4) product labeling; (5) storage and disposal of biohazards and/or medical waste; (6) irradiation; and (7) sterilization and aseptic processing.

Proposed § 1271.190(c) contains basic requirements for facility cleaning and sanitation. Facilities must be maintained in a clean, sanitary, and orderly manner. Sewage, trash, and other refuse must be disposed of in a timely, safe, and sanitary manner. Procedures for facility cleaning and sanitation would be required to be established and maintained. These procedures would need to include an assignment of responsibility for sanitation, cleaning methods to be used, and a cleaning schedule. Finally, all significant cleaning and sanitation activities that are done to prevent contamination would need to be documented, and records maintained.

2. Environmental Control and Monitoring (Proposed § 1271.195)

Proposed § 1271.195 would require monitoring and control over environmental conditions where such conditions (e.g., temperature, air quality) could reasonably be expected to have an adverse effect on the function or integrity of human cellular and tissue-based products, to cause contamination or cross-contamination of products or equipment, or to lead to accidental exposure of products to communicable disease agents. In these situations, an establishment would be required to establish and maintain procedures to adequately control and monitor environmental conditions and to provide proper conditions for operations.

Depending on the particular environmental factors at a facility, and the type of operations that take place there, environmental controls and monitoring could include one or more of the following: Temperature and humidity controls; ventilation and air filtration; cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations; maintenance of equipment used to control conditions necessary for aseptic processing operations; and environmental monitoring for organisms. Proposed § 1271.195(a) would require these elements to be adopted, where appropriate. Thus, under proposed § 1271.195, an establishment would be required first to identify any environmental conditions that require monitoring and control, and then to respond appropriately.

Periodic inspections of environmental controls systems would be required. In addition, environmental controls and monitoring activities would have to be documented, and records maintained.

3. Equipment (Proposed § 1271.200)

CGTP requirements for equipment are set out in proposed § 1271.200. For human cellular and tissue-based products to be manufactured properly, the equipment used in their manufacture must be appropriate. Thus, § 1271.200(a) contains the general requirement that equipment used in the manufacture of human cellular and tissue-based product be of appropriate design for its use. Equipment must be suitably located and installed to facilitate operations, including cleaning and maintenance. In addition, equipment must not have any adverse effect on the products being manufactured.

Equipment used for inspection, measuring, and testing must be capable of producing valid results; such equipment could include automated, mechanical, electronic, computer, or other kinds of equipment. Section 1271.200(c) would require regularly scheduled calibration of equipment used for inspection, measuring, and testing. Thus, for example, a thermometer used in a storage area would be required to produce valid results and would also be subject to regularly scheduled calibration procedures. ''Equipment used for inspection'' would include any equipment used to inspect a human cellular or tissue-based product during its manufacture or prior to making it available for distribution.

Under § 1271.200(b), an establishment would be required to establish and maintain procedures for cleaning, sanitizing, and maintaining equipment. The purpose of these procedures is to prevent equipment malfunctions, contamination or cross-contamination, accidental exposure of human cellular and tissue-based products to communicable disease agents, and other events that could reasonably be expected to have an adverse effect on product function or integrity. Cleaning, sanitizing, and maintenance of equipment would be required to be performed according to established schedules.

Section 1271.200(d) sets out a requirement for routine inspections of equipment for cleanliness, sanitation, and calibration, and to ensure compliance with maintenance schedules.

Section 1271.200(e) contains specific requirements for records, to be maintained in accordance with the general records provisions in § 1271.270. All maintenance, cleaning, sanitizing, calibration, and other activities performed in accordance with § 1271.200 would be required to be documented. Records of recent maintenance, cleaning, sanitizing, calibration, and other activities must be available at each piece of equipment; this requirement promotes both accurate recordkeeping and ease of reference. In addition, the use of each piece of equipment must be documented, and this record of use must identify each human cellular or tissue-based product manufactured using the equipment. This requirement is necessary to ensure that those products manufactured with a particular piece of equipment may be traced for follow-up and appropriate corrective action, in the event that a problem (e.g., contamination or malfunction) is discovered after the equipment is used.

4. Supplies and Reagents (Proposed § 1271.210)

Use of a contaminated or otherwise defective supply or reagent in the manufacture of a human cellular or tissue-based product could adversely affect the product; e.g., by introducing a disease agent or by failing to properly preserve the product. For this reason, compliance with CGTP requires that care be taken in receiving supplies and reagents into an establishment, in determining their appropriateness for use, and in keeping track of the products in whose manufacture they are used. By ''supplies and reagents,'' the agency refers to all of the products that might be used during the manufacturing process but excludes any material that might be considered to become a component of a human cellular or tissue-based product. Supplies and reagents would include, but not be limited to, ''processing material,'' which the agency is proposing to define at § 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 human cellular or tissue-based product when it is made available for distribution.''

Proposed § 1271.210 contains several requirements with respect to supplies and reagents used in the manufacture of human cellular and tissue-based products. An establishment would be required to establish and maintain procedures for receiving supplies and reagents. Before using a supply or reagent, the establishment must verify that the supply or reagent meets specifications that are designed to prevent circumstances that increase the risk of the introduction, transmission, and spread of communicable disease through product contamination or the impairment of product function or integrity. An establishment could verify on its own that the supplies and reagents that it uses meet specifications; e.g., by testing the product. Alternatively, verification could be accomplished by the vendor of the supply or reagent. ''Verification'' is defined in proposed § 1271.3(ss) as ''confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.''

Section 1271.210(b) would require that reagents used in processing and preservation of human cellular and tissue-based products be of appropriate grade for their intended use and, if appropriate, sterile. Some establishments may produce their own in-house reagents. These establishments would be required to validate and/or verify the procedures for producing such reagents.

Section 1271.210(c) would require that specific records relating to the receipt, verification, and use of each supply and reagent be maintained.

G. Processing

Three sections of the proposed CGTP regulations address the processing of human cellular and tissue-based products. Proposed § 1271.220 would require controls to be established over processing. Requirements for making changes to processes are contained in proposed § 1271.225. Proposed § 1271.230 would require process validation in place of verification in some situations and sets out certain specific requirements related to process validation.

''Processing'' is defined in proposed § 1271.3(mm) as ''any activity other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution performed on a human cellular or tissue-based product, including, but not limited to, preparation, sterilization, steps to inactivate and remove adventitious agents, preservation for storage, and removal from storage.''

1. Process Controls (Proposed § 1271.220)

Under proposed § 1271.220(a), any establishment engaged in the processing of human cellular and tissue-based products would be required to develop, conduct, control, and monitor its manufacturing processes to ensure that each product: (1) Conforms to its specifications, (2) is not contaminated, (3) maintains its function and integrity, and (4) is manufactured so as to prevent transmission of communicable disease by the product. By ''specifications,'' the agency refers to those criteria established by a manufacturer for a human cellular or tissue-based product that must be met at defined stages in the manufacturing process and before the product is made available for distribution.

Sections 1271.220(b) governs the removal of processing materials. In accordance with the definition proposed in § 1271.3(hh), processing materials would not be intended by the manufacturer to be included in a human cellular or tissue-based product when it is made available for distribution. Under § 1271.220(b), where a processing material could reasonably be expected to have an adverse effect on a human cellular or tissue-based product's function or integrity, the establishment would be required to establish and maintain procedures for the use and removal of the processing material to ensure that it is removed or limited to an amount that does not adversely affect the product's function or integrity. Any such removal or reduction would be required to be documented.

Section 1271.220(c) would prohibit the pooling of human cells or tissue from two or more donors during manufacturing. Pooling refers to placing products in physical contact with each other or mixing them in a single receptacle. Such commingling of cells or tissues from a single infected donor with cells or tissues from other donors can contaminate the entire pooled quantity, greatly increasing the risk to recipients of the pooled materials of exposure to infectious agents. The proposed regulation is consistent with recommendations made by FDA's Transmissible Spongiform Encephalopathy Advisory Committee, at their meeting on October 6, 1997, with respect to the pooling of dura mater.

Section 1271.220(d) would require procedures to be established for in-process monitoring, or monitoring of the product during processing, for compliance with specified requirements. This requirement is modified by the phrase ''where appropriate.'' In other words, as discussed in section II.A.4. of this document, in-process monitoring would be required unless the establishment can justify, and document, that it would be unnecessary under the terms of § 1271.150(d). The in-process product would have to be controlled until the completion of any required inspection, tests, or other verification activities, or until any necessary approvals are received and documented. Any sampling taken of the in-process product for the purpose of testing or inspection would be required to be representative of the material being evaluated.

2. Process Changes (Proposed § 1271.225)

Proposed § 1271.225 would require an establishment to establish procedures for making changes to a process. Any such change would have to be verified or validated, to ensure that the change does not create an adverse impact elsewhere in the operation. Any change would also have to be approved by a responsible person with appropriate knowledge and background before being implemented. Proposed § 1271.225(b) would require that records be kept of all such changes, and sets out the required elements of such records (e.g., the rationale for the change).

3. Process Validation (Proposed § 1271.230)

Proposed § 1271.230 contains requirements related to the validation of processes. Process validation, under proposed § 1271.3(rr), means ''establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.''

Proposed § 1271.230(a) would require establishments to validate their processes where verification is not feasible; e.g., where verification cannot be performed on each and every finished product. Thus, § 1271.230(a) states that, where the results of a process cannot be fully verified by subsequent inspection and tests, the process must be validated and approved according to established procedures, and the validation activities must be documented.

Under § 1271.230(b), any claim made in labeling or promotional materials that is related to the process used to manufacture a human cellular or tissue-based product must be based on a process that has been validated. Validation must be documented, and evidence of the validation must be maintained at the establishment and made available for review on inspection. Examples of such process-related claims

include the claim that a product is sterile or that it has undergone viral inactivation.

The agency is proposing in § 1271.230(c) a requirement that would apply specifically to establishments that process dura mater. Donor screening and testing requirements for donors of dura mater have been proposed in the donor-suitability proposed rule, but additional processing safeguards are necessary to prevent the transmission of Creutzfeldt-Jakob disease (CJD) (64 FR 52696 at 52706). Proposed § 1271.230(c) would require that dura mater be processed using a validated procedure to reduce CJD infectivity, while preserving the clinical utility of the product. Currently, an example of such a procedure would be a sodium hydroxide (NaOH) protocol that has been validated to reduce CJD infectivity (in an animal model) while preserving the tissue's clinical utility. In the future, other methods that more effectively reduce CJD infectivity may be developed.

If processes are validated, in place of verification, then procedures must be established and maintained to ensure that the specified requirements continue to be met; this requirement appears in proposed § 1271.230(d). Under § 1271.230(e), any change or deviation from a validated process would require a review and evaluation of the process and, where appropriate, revalidation.

H. Labeling Controls (Proposed § 1271.250)

Under proposed § 1271.250, an establishment would be required to establish and maintain procedures to control the labeling of human cellular and tissue-based products. These control procedures would be designed to ensure that products are identified properly and to prevent mix-ups. The agency is not specifying how such controls should be designed, but notes that they would likely need to include such elements as proper storage methods to prevent deterioration of adhesives, among other problems. In addition, § 1271.250 would require procedures to include verification of label accuracy, legibility, and integrity. Thus, for example, a labeled product would be checked under such verification procedures to ensure that its label was affixed securely to the container, could be read with ease, and accurately identified the product by identifier and product type.

Proposed § 1271.250 would also require that procedures be established and maintained to ensure that products are labeled in accordance with all applicable labeling requirements. ''Applicable labeling requirements'' for human cellular and tissue-based products regulated as biological drugs include the labeling regulations in parts 201 and 610 (21 CFR parts 201 and 610); for products regulated as devices, they include those in part 801 (21 CFR part 801). Other labeling requirements appear in several sections of proposed part 1271, and these are listed in proposed § 1271.250. For example, § 1271.90 is cross-referenced in § 1271.250; it would require that banked cells and tissues for autologous use be labeled ''FOR AUTOLOGOUS USE ONLY'' (donor-suitability proposed rule (64 FR 52723)). Procedures established in compliance with proposed § 1271.250 would need to ensure that banked cells and tissues for autologous use were labeled with this statement.

I. Storage (Proposed § 1271.260)

Proposed § 1271.260 sets out storage requirements. The proposed regulation addresses three general areas of concern: Control of storage areas; storage temperature; and expiration date.

Under proposed § 1271.260, each establishment would be required to establish and maintain procedures for the control of storage areas and stock rooms in order to prevent mix-ups, commingling, deterioration, contamination, and cross-contamination of human cellular and tissue-based products and supplies, as well as any other condition that might adversely affect product function or integrity. In addition, controls would be required to prevent improper release for distribution.

Storage at a proper temperature, in order to preserve a product's function and integrity and prevent deterioration, is an important aspect of CGTP. FDA recognizes that appropriate temperatures may differ for various types of products. Thus, § 1271.260(b) would require an establishment to establish acceptable temperature limits for the storage of human cellular and tissue-based products at each step of the manufacturing process. Monitoring of storage temperatures would be required. Temperatures would have to be documented, and recorded temperatures reviewed periodically to assure that temperatures remained in the permissible range.

Different products may be stored for differing lengths of time before use. The maximum storage period depends on such factors as product type, processing procedures and method of preservation, storage conditions, and type of packaging. Section 1271.260(c) would require, where appropriate, that an expiration date be assigned for each human cellular or tissue-based product.

Under § 1271.260(d), corrective action must be taken and documented whenever proper storage conditions are not met.

J. Receipt and Distribution (Proposed § 1271.265)

Proposed § 1271.265 covers the receipt and distribution of human cellular and tissue-based products. Section 1271.265(a) contains general requirements for procedures and recordkeeping. Section 1271.265(b) governs receiving activities. Requirements that must be met prior to making a product available for distribution are contained in § 1271.265(c). The remaining paragraphs deal with packaging, shipping conditions, and the return of products to inventory.

Under § 1271.265(a), procedures would be required for receiving, accepting or rejecting, and distributing human cellular and tissue-based products, as well as for the destruction or other disposition of such products. Each of these activities, when performed, must be documented. Required documentation would include the identification of the human cellular or tissue-based product, the activities performed and the results of such activities, the date or dates of the activity, the quantity of product subject to the activity, and the disposition of the product. The disposition of the product would include, for example, the identity of the consignee. Complete and accurate identification of a consignee would include not only the consignee's name, but its address and telephone number.

Section 1271.265(b) contains specific requirements with respect to the receipt of human cellular and tissue-based products for processing, distribution, or any other step in the manufacturing process. As part of its receiving activities, an establishment would be required to inspect incoming human cellular and tissue-based products, according to established procedures, for damage, contamination, deterioration, or any other indication that the integrity of the product had been impaired. The establishment would then determine whether to accept or reject the product. Acceptance or rejection of the incoming product would need to be documented.

An establishment receiving a human cellular or tissue-based product would also be required to ascertain its status and handle the product appropriately. For example, a product that is shipped under quarantine, pending completion of the donor-suitability determination required under subpart C of part 1271,

would be required to be maintained in quarantine after its receipt until the determination was complete. Other issues of product status (e.g., stage in processing, results of donor screening and testing) would dictate other appropriate action with respect to the product.

Proposed § 1271.265(c) deals with an establishment's determination that a product is ''available for distribution,'' a term that the agency is proposing to define in proposed § 1271.3(ff). Under that definition, a human cellular or tissue-based product is ''available for distribution'' if it has been determined to meet all release specifications and to be suitable for distribution. Under § 1271.265(c), an establishment would be required to establish and maintain procedures for making products available for distribution, including developing release criteria. These procedures would be designed to prevent the release of products that are in quarantine, have deteriorated, or otherwise have been manufactured in violation of CGTP. They must also prevent the release of products from donors who have not been determined to be suitable, except as provided under proposed §§ 1271.65 and 1271.90.

Prior to making a human cellular or tissue-based product available for distribution, an establishment would be required to review all records pertaining to the product and to verify and document that release criteria have been met. The determination that a product is available for distribution must be documented and dated by a responsible person.

Under § 1271.265(d), all packaging and shipping containers would be required to be designed, validated, and constructed so as to ensure product function and integrity and to protect the product from damage, deterioration, contamination, or other adverse effects during customary conditions of processing, storage, handling, and distribution. Section 1271.265(e) would require that appropriate shipping conditions, to be maintained during transit, be defined for each type of product. And § 1271.265(f) would require that an establishment develop procedures for determining whether a product that is returned to the establishment may be returned to inventory.

K. Records (Proposed § 1271.270)

Proposed § 1271.270 contains general requirements for recordkeeping under part 1271. Section 1271.270(a) would require establishments to maintain records concurrently with the performance of each significant step required in subparts C and D of part 1271. Many, but not necessarily all, of the requirements for documenting a manufacturing activity are specifically noted elsewhere in the regulations. For example, an establishment's receipt of tissue for processing would be a significant step that needs to be documented; proposed § 1271.265(a) lists the specific documentation that would be required. As noted in proposed § 1271.270(a), any requirement in part 1271 that an activity be documented involves the creation of a record, and that record would be subject to the requirements of § 1271.270.

Section 1271.270(a) would require records to be accurate, indelible, and legible. Entries must be dated and the person performing the work in question must be identified. Records would have to be sufficiently detailed to provide a complete history of the work performed and to relate the records to the particular human cellular or tissue-based product involved. In order to protect the privacy of both donors and recipients, adequate record security systems would be required.

Under § 1271.270(b), establishments would have the flexibility to develop individualized systems of maintaining and organizing their records, so long as certain objectives were achieved. Records could be maintained in more than one location, provided that the records management system was designed to ensure prompt identification, location, and retrieval of all records. Further, the records management system would need to facilitate the review of a particular human cellular or tissue-based product's history both prior to its release for distribution and, if necessary, at a later date as part of a follow-up evaluation or investigation. In addition to records pertaining to individual products, records for product types would be required to be maintained and organized. Thus, for example, a manufacturer of several different types of human cellular and tissue-based products would be required to maintain, for each product type, records of pertinent procedures, product specifications, labeling and packaging procedures, and equipment logs. A records management system could be as simple as keeping all information pertaining to the manufacture of one product in one file folder, and keeping all file folders for one product type, e.g., tendons, in one drawer of the file cabinet. This drawer, labeled ''Tendons'', would also contain a folder for ''generic'' procedures common to all tendons. A more elaborate records management system could utilize a computer to generate files and subfiles.

Section 1271.270(d) and (e) deal with methods and time frames for retaining records. Under § 1271.270(d), records could be maintained electronically, as original paper records, or as true copies. Examples of true copies include photocopies, microfiche, and microfilm. Suitable equipment would be required to be available for reading and photocopying any records maintained on microfiche or microfilm. Records stored in automated data processing systems must be backed up to prevent their loss. Any electronic record or electronic signature would be subject to the requirements in 21 CFR part 11.

Under § 1271.270(e), all records would be required to be kept for 10 years after their creation. However, consistent with proposed § 1271.55(b) on records of donor-suitability determinations, records pertaining to a particular human cellular or tissue-based product must be retained at least 10 years after the date of implantation, transplantation, infusion, or transfer of the product. See donor-suitability proposed rule (64 FR 52721). If the date of implantation, transplantation, infusion, or transfer is not known, then the records must be retained at least 10 years after the date of the product's distribution, disposition, or expiration, whichever is latest. The establishment must make provisions for all records to be maintained for the required period in the event that the establishment ceases operation. FDA requests comment on whether there are specific types of records for which a retention period shorter than 10 years would be appropriate and would not compromise the agency's ability to prevent the introduction, transmission and spread of communicable disease.

Section 1271.270(c) cross-references records requirements proposed in subpart C of part 1271 that relate to donor testing and screening, in order to make clear that records required under subpart C of part 1271 are subject to the recordkeeping requirements in § 1271.270. Section 1271.270(f) would require an establishment to maintain records of contracts, agreements, and other arrangements with other establishments under which any step in the manufacturing process is performed by the other establishment. These records would need to contain not only the name and address of the other establishment, but also a description of each party's responsibilities.

L. Tracking (Proposed § 1271.290)

FDA considers product tracking to be an essential component of its proposed

regulatory system for human cellular and tissue-based products. Should the recipient of such a product contract a communicable disease, tracking would permit appropriate follow-up, such as an investigation to determine whether the human cellular or tissue-based product transmitted the disease agent and, if so, would permit steps to be taken to prevent the distribution of other similarly infected products. Similarly, if a donor is discovered, post-donation, to have had a communicable disease, tracking would permit an establishment to locate products from that donor. Thus, a tracking system is closely linked to the agency's regulatory objective of preventing the spread of communicable disease.

As with other components of these CGTP regulations, FDA is proposing certain basic requirements, but is allowing establishments flexibility in designing tracking programs that suit their particular activities. Auditing of an establishment's tracking method to ensure its effectiveness would be required under the quality program (proposed § 1271.160(b)(8) and (d)). FDA recognizes that some establishments have already developed and implemented tracking systems and requests comments from those establishments on the success or failure of particular tracking methods.

Part 821 (21 CFR part 821) of FDA's regulations contains the medical device tracking requirements. Except for dura mater, human cellular and tissue-based products regulated as devices generally have not been subject to tracking under part 821; thus, there will be little or no duplication of tracking requirements. When a human cellular or tissue-based product is designated as a ''tracked device,'' and subject to the device tracking regulations, the manufacturer would be required to satisfy both sets of tracking requirements. However, given the variety of methods that could be devised to satisfy the tracking requirements proposed in § 1271.290, it is foreseeable that a single tracking method could be adopted that conforms with the requirements of both § 1271.290 and part 821.

Proposed § 1271.290 would require each human cellular or tissue-based product to be tracked. Section 1271.290(a) would place the tracking obligation on each establishment that performs any step in the manufacture of a human cellular or tissue-based product.

Proposed § 1271.290(b) would require the establishment to establish and maintain a method of product tracking that enables the tracking of all human cellular and tissue-based products from the donor to the recipient or final disposition and conversely from the recipient or final disposition to the donor. FDA recognizes, however, that some establishments may be better equipped than others to establish an effective tracking system. For this reason, the agency proposes to permit an establishment that performs some, but not all, of the steps in the manufacturing process to participate in a method of product tracking that has been established by another establishment responsible for other steps in the manufacturing process, provided that the tracking method meets all the requirements of § 1271.290. One possible method of tracking would be to collect information about recipients on cards that are returned to the tracking establishment.

Section 1271.290(c) would require that each human cellular or tissue-based product be assigned and labeled with a distinct identification code (e.g., alphanumeric) that relates the product to the donor and to all records pertaining to the product. Except in the case of autologous or directed donations, such a code must be created specifically for tracking and may not include an individual's name, social security or medical record number. An establishment that receives a human cellular or tissue-based product for further manufacturing might use the code already assigned or might assign a new identifier to the product. The regulation specifies, however, that an establishment that assigns a new identifier to a product shall establish and maintain procedures for relating the new identifier to the old identifier.

Section 1271.290(d) would require establishments to ensure, through agreements with consignees or through other measures, that the code and type of each human cellular or tissue-base product that is implanted, transplanted, infused, or transferred 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. Section 1271.290(e) would require an establishment to document and maintain records of the disposition of each of its human cellular or tissue-based products to enable tracking from the donor to the recipient or final disposition. The information to be maintained must permit the prompt identification of the recipient of the product.

Under § 1271.290(f), an establishment would be required to inform its consignees in writing of the requirements in § 1271.290 and of the tracking method that the establishment is using to comply with those requirements. For example, a statement might be included in the materials accompanying the consigned human cellular or tissue-based product that would describe applicable regulations and the establishment's tracking method. The establishment would 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; this agreement would need to be obtained and documented upon initial distribution of human cellular or tissue-based products to a consignee and would not need to be obtained for each subsequent consignment.

Proposed § 1271.290(g) contains a requirement specific to donors of dura mater, intended to address the particular communicable-disease concerns associated with that type of product. Appropriate specimens from the dura mater donor would be required to be archived, under appropriate storage conditions, and for the appropriate duration, to enable future testing of the archived material for evidence of transmissible spongiform encephalopathy (TSE) and appropriate disposition of any affected dura mater tissue, if necessary. Although archiving samples may not immediately increase the assurance of safety for a dura mater graft, it would permit later testing for TSE-induced changes using improved or new methods as they become available. In the event that a dura graft recipient became ill with CJD, such testing of archival donor material would be needed to confirm whether the dura graft was the source of infection, so that no additional grafts from the affected lot would be distributed. At this time, based on currently available information, FDA recommends that samples of donor brain and dura mater tissues be archived at a temperature equal to or less than minus 70 ½C for 16 years beyond the product's expiration date.

Ideally, archived samples should be retained for the lifetime of the graft recipient, because the maximum incubation period is not certain. To date, the longest known incubation period is 16 years (Ref. 1). FDA believes that it may be unrealistic to expect a manufacturer to maintain an archive for such a long time. FDA suggests that establishment of a nationally supported archive be considered for prolonged storage of these materials, in order to further the study of iatrogenic transmission of spongiform encephalopathies.

M. Complaint Files (Proposed § 1271.320)

Proposed § 1271.320 would require establishments to maintain records of, and review, all complaints. ''Complaint'' is defined in proposed § 1271.3(ii) as:

any written, oral, or electronic communication that alleges: (1) that a human cellular or tissue-based product has transmitted or may have transmitted a communicable disease to the recipient of the product; (2) that the function or integrity of a human cellular or tissue-based product may have been impaired; or (3) any other problem with a human cellular or tissue-based product that could result from the failure to comply with current good tissue practice.

A communication from a physician expressing concern about possible product contamination would be a ''complaint.''

The proposed regulation would require establishments to establish and maintain procedures for the prompt review, evaluation, and documentation of all complaints. Records of each complaint that the establishment receives would be required to be maintained in a file designated for complaints. The complaint file would be required to contain sufficient information about each complaint for proper review and evaluation of the complaint, including the identifier of the human cellular or tissue-based product that is the subject of the complaint. For example, the complaint file should include the date of each report, the unique product identifier, and the name of the person or establishment that submitted the complaint. Proposed § 1271.320 would require that the complaint file be made available for review and copying upon request from an authorized employee of FDA. Section 1271.320(c) sets out requirements for the review and evaluation of complaints.

III. Additional Requirements With Respect to 361 Products

Proposed subpart E of part 1271 contains reporting and labeling requirements that would apply only to those establishments that manufacture human cellular and tissue-based products as described in proposed § 1271.10 (registration proposed rule (63 FR 26754)). Such products would be products that: (1) Are minimally manipulated, (2) are not promoted or labeled for any use other than a homologous use, (3) are not combined with or modified by the addition of any nontissue or noncellular component that is a drug or a device, and (4) do not have a systemic effect. The agency proposes to regulate such products solely under the authority of section 361 of the PHS Act and not as biological drugs or devices. Thus the heading of subpart E of part 1271 is ''Additional Requirements for Establishments Described in § 1271.10.'' Human cellular and tissue-based products regulated as biological drugs or as medical devices will continue to be subject to reporting and labeling requirements that are currently in place.

Although the title of proposed subpart E of part 1271 refers to ''additional'' requirements for establishments described in § 1271.10, the proposed reporting and labeling requirements are designed to be less extensive and burdensome than the current requirements applicable to products regulated as biological drugs or as devices. This approach is in keeping with the agency's expressed plans to put in place a tiered regulatory scheme, under which human cellular and tissue-based products would be subject to an appropriate level of regulation based on the degree of risk. At the same time, the proposed reporting and labeling requirements for 361 products have been drafted to be generally consistent with existing biological drug and device regulations.

A. Reporting Requirements (Proposed § 1271.350)

In order to stay informed of potential problems with human cellular and tissue-based products related to communicable-disease transmission, and to be able to take appropriate steps in response, FDA needs to receive information from establishments on adverse reactions and certain product deviations that could result in adverse reactions. For this reason, FDA is proposing to require two different kinds of reports from establishments that manufacture human cellular and tissue-based products regulated solely under section 361 of the PHS Act: the reporting of adverse reactions, and the reporting of product deviations.

1. Adverse Reactions

Under proposed § 1271.350(a), establishments would be required to report adverse reactions to CBER. The agency is engaged in an ongoing effort to enhance agency-wide consistency in the collection of safety data and, where possible, consistency with the definitions, reporting periods, formats, and standards recommended by the International Conference on Harmonisation of Technical Requirements of Registration of Pharmaceuticals for Human Use (ICH). See ''Expedited Safety Reporting Requirements for Human Drug and Biological Products,'' final rule (62 FR 52237, October 7, 1997). In order to achieve a degree of uniformity throughout the agency and to simplify reporting requirements for firms, FDA has modeled the procedures in § 1271.350(a) on the reporting requirements for other regulated products (i.e., drugs, devices, and biological products) and is proposing to require use of the same standard reporting form that is already in use (FDA Form-3500A).

Proposed § 1271.3(gg) would define an adverse reaction as ''a noxious and unintended response to any human cellular or tissue-based product 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).'' This definition reflects the agency's intention to shift from adverse experience reporting to adverse reaction reporting, consistent with ICH guidelines (62 FR 52237 at 52238), and is consistent with the ICH E2A guideline's definitions of ''adverse drug reaction,'' International Conference on Harmonisation; Guideline on Clinical Safety Data Management; Definitions and Standards for Expedited Reporting, availability (60 FR 11284 at 11285, March 1, 1995). Under the proposed definition, not all unsuccessful outcomes would be considered ''adverse reactions.'' For example, the agency recognizes that a recipient may reject a human cellular or tissue-based product, or that there may be a failure to engraft (e.g., of hematopoietic stem cells), for reasons that are unrelated to the product itself. Or a procedure may fail for reasons that, whether or not specifically identified, are known not to be product-related. On the other hand, if the relationship between the product and the noxious and unintended response cannot be ruled out, the response would be considered an adverse reaction under the proposed definition.

The phrase ''the relationship cannot be ruled out'' is included in the proposed definition to clarify which individual cases should be reported to FDA. Instances of probable, possible, remote, or unlikely relationships would all be considered adverse reactions, because there would be at least a reasonable possibility that the noxious and unintended response may have been caused by the human cellular or tissue-based product, even though causality has not been established.

Under proposed § 1271.350(a), only those adverse reactions that involved the transmission of a communicable

disease, product contamination, or the failure of a human cellular or tissue-based product's function or integrity would be required to be reported. Moreover, reporting would be limited to those adverse reactions that are fatal or life-threatening, that result in permanent impairment of a body function or permanent damage to body structure, or that necessitate medical or surgical intervention.

In order to determine which adverse reactions are required to be reported, each establishment would be required to review all adverse reaction reports. The source of the information is not relevant; all reports, regardless of source, would have to be considered.

The procedures proposed for reporting adverse reactions are modeled on those used for other products regulated by the agency. Reports to the agency would be required within 15 calendar days of initial receipt of the information, with a possible follow-up report. Reports would be submitted to CBER. The proposed regulation provides addresses and information on obtaining forms.

With respect to human cellular and tissue-based products regulated as biological drugs, the reporting requirements in 21 CFR 600.80 continue to apply. For those products regulated as devices, the medical device reporting requirements in 21 CFR part 803 apply. The agency notes that the transmission of a serious communicable disease would constitute an event that is required to be reported under current regulations.

2. Product Deviations

FDA is proposing to require, in § 1271.350(b), that those product deviations that could reasonably be expected to lead to a reportable adverse reaction be reported to CBER, along with information on corrective actions. A definition of the term ''product deviation'' is proposed in § 1271.3(kk) and has been discussed at section II.C of this document.

In the proposed approach document, FDA indicated that establishments would be required to maintain records of errors and accidents, a term that is incorporated in this proposal within the meaning of ''product deviation'' (see proposed § 1271.3(kk)), and to make them available for inspection, but that no reports to the agency would be required. The General Accounting Office, in its report on human tissue banks, criticized the agency for not requiring that such records be reported (Ref. 2).

The agency is now proposing to require the reporting of certain product deviations: those that are of the type that could reasonably be expected to lead to a reportable adverse reaction. In addition, required reporting would be limited to product deviations involving human cellular or tissue-based products that have been distributed. The agency considers that these limitations on the reporting obligation will lessen the burden on establishments and on the agency, making it possible for the agency to receive meaningful information and respond appropriately (e.g., by monitoring recalls and assisting in their implementation as necessary and appropriate).

Proposed § 1271.350(b) sets out the requirements for reporting product deviations that could give rise to an adverse reaction and provides the address to be used. Reports of such product deviations would be expected as soon as possible. Although no particular reporting form would be required, § 1271.350(b)(2) states that each report shall contain a description of the product deviation and information on all corrective actions that have been or will be taken in response to the product deviation, such as recalls.

B. Labeling and Claims

Proposed § 1271.370 contains requirements for product labeling and would govern promotional claims made for human cellular and tissue-based products regulated solely under the authority of section 361 of the PHS Act. Section 1271.370(a) describes the required contents of product labels and accompanying materials. The types of claims that may be made for human cellular and tissue-based products are addressed in § 1271.370(b).

The agency considers regulation of labeling and promotion to be an essential part of its proposed tiered, risk-based regulatory system for human cellular and tissue-based products.

Labeling and promotional materials which contain incomplete, unclear, inaccurate, unbalanced, or misleading information can increase the risk of the introduction, transmission, or spread of communicable disease by misleading the public into inappropriate or unsafe practices regarding these products (e.g., storing a product at an incorrect temperature) or by hindering corrective action which might become necessary (e.g., by delaying identification of the establishment distributing an unsafe product).

For these reasons, the agency considers that section 361 of the PHS Act provides the agency with sufficient authority to issue these requirements.

1. Labeling Information

Proposed § 1271.370(a) would require each human cellular or tissue-based product made available for distribution to be labeled clearly and accurately. In addition, certain basic information would be required to appear on the product label: (1) The name and address of the establishment that determined that the product met release criteria and made the product available for distribution, (2) a description of the type of product, and (3) the product's expiration date, if any. The agency considers each of these items to be of sufficient importance that they warrant placement on the product label itself instead of in materials that accompany the product. The first two items are crucial for accurately identifying the product and responsible establishment in the event of any necessary follow-up action (e.g., adverse reaction reports). Requiring products to be labeled with their expiration dates helps to ensure that they maintain their function and integrity at the time of use.

Recognizing that space on the product label may be limited, the agency proposes to require that the following information appear either on the product label or in a package insert: (1) Storage temperature, (2) warnings, where appropriate, and (3) instructions for use. Information on storage temperature will help prevent errors in handling and help ensure that the product maintains its integrity and functions properly in the recipient. Warnings and instructions for use will inform the physician of the proper use of the product and would increase the probability of a successful procedure.

2. Claims

Section 1271.370(b) deals with claims for human cellular and tissue-based products in labeling, advertising, and promotional materials. Consistent with the agency's plans outlined in the proposed approach document, this provision would require that any such claim be clear, truthful, balanced, and not misleading. A ''balanced'' claim for a product would, for example, reflect an objective, unbiased view of the product, including not only claims for the product's benefits but also explanations of any hazards. A claim may be considered to be misleading if it omits important information.

Proposed § 1271.370(b)(2) is intended to clarify one of the four criteria that must be met for a human cellular or tissue-based product to be regulated solely under the authority of section 361 of the PHS Act. Under proposed § 1271.10, a 361 product is one that, in

addition to meeting other criteria, is not promoted or labeled for any use other than a homologous use (registration proposed rule (63 FR 26744 at 26754)). Section 1271.370(b)(2) explains that a labeling claim or promotional materials regarding the therapeutic or clinical outcome of a human cellular or tissue-based product (other than for reconstruction, replacement, repair, or supplementation of cells or tissue) would be considered a claim for a use other than a homologous use. A product for which such a claim was made would be subject, along with its labeling, to regulation under the act and/or section 351 of the PHS Act.

3. Labeling of Biological Drugs and Devices

Proposed § 1271.370 applies only to 361 products; human cellular and tissue-based products regulated as biological drugs or as devices will continue to be subject to labeling requirements currently in place. Parts 201 and 610 (21 CFR parts 201 and 610) will apply to human cellular or tissue-based products regulated as biological drugs, as will relevant statutory provisions and any conditions of product licensure. Human cellular and tissue-based products regulated as devices will be subject to the labeling requirements in part 801, in addition to the provisions of the act and any applicable conditions of approval or clearance.

In order to ensure that all human cellular and tissue-based products, regardless of regulatory category, bear certain basic relevant information, FDA proposes to interpret several current regulations as encompassing the information set out in proposed § 1271.370(a). The agency would expect the information listed in proposed § 1271.370(a) to appear on the label or package insert of those products regulated as biological drugs or devices.

The paragraphs below set out each item listed in proposed § 1271.370(a), along with the parallel regulation applicable to biological drugs or devices. The agency expects that few if any changes will need to be made to current labeling to ensure that the information listed in proposed § 1271.370(a) is provided. Where there is a difference in required placement of the information (e.g., on the label or in a package insert), the placement required in the biological drug or device regulation will apply.

a. *Name and address of the establishment that determines that the product meets release criteria and makes the product available for distribution*. For biological drugs, §§ 610.60(a)(2), 610.61(b), and 610.63 require the name, address, and license number of the manufacturer or, in the case of divided manufacturing responsibilities, all manufacturers. Section 610.64 permits the name of the distributor to appear. For human cellular and tissue-based products, FDA considers the establishment that determines that the product meets release criteria and makes the product available for distribution to be a manufacturer and will expect that manufacturer's name and address to appear on the product label.

Section 801.1(a) requires the label of a device to specify the name and place of business of the manufacturer, packer, or distributor. FDA proposes to interpret this requirement, with respect to human cellular and tissue-based products regulated as devices, as requiring the name of the establishment that determines that the product meets release criteria and makes the product available for distribution.

b. *Description of the type of product*. For biological drugs, §§ 610.60(a)(1) and 610.61(a) require the proper name of the product to appear on the container and package label. The product's proper name will serve as an adequate description of the type of product. For devices, section 502(e)(2) and (e)(4) of the act (21 U.S.C. 352(e)(2) and (e)(4)) requires products to be labeled with their established name, or if there is no established name, then with the common or usual name of the device; either will suffice, so long as it adequately describes the type of product.

c. *Expiration date*. For biological drugs, §§ 610.60(a)(4) and 610.61(d) require products to be labeled with their expiration dates. For devices, § 801.109(c) requires products to be labeled with information on ''any relevant * * * precautions''; FDA proposes to interpret this provision as requiring a product's expiration date, if the product has one, because the expiration date is effectively a precaution against use of an out-of-date product.

d. *Storage temperature*. For biological drugs, § 610.61(h) requires the recommended storage temperature to appear on the package label. For devices, FDA proposes to interpret § 801.109(c), which requires information for use, including precautions, to include the proper storage temperature.

e. *Warnings, where appropriate*. For biological drugs, § 210.57(e) requires warnings. For devices, § 801.109(c) requires information on hazards, contraindications, side effects, and precautions, which FDA proposes to interpret as including any appropriate warnings.

f. *Instructions for use*. For biological drugs, § 610.61(i), (j), and (k), as well as § 201.57(c), requires instructions for use. For devices, instructions for use are required in § 801.109(b)(2) and (c).

IV. Inspection and Enforcement Provisions

Proposed subpart F of part 1271 contains provisions on inspections; human cellular and tissue-based products offered for import; and orders of retention, recall, destruction, and cessation of manufacturing. Subpart F of part 1271 would apply only to those establishments described in proposed § 1271.10; i.e., those establishments that manufacture human cellular and tissue-based products regulated under the authority of section 361 of the PHS Act and proposed part 1271, but not as biological drugs or as devices. Products that the agency is regulating as devices or biological drugs will be subject to the enforcement provisions of the act and applicable regulations.

The proposed inspection and enforcement provisions are based on those contained in part 1270, subpart D, which are currently applicable to human tissue intended for transplantation. These provisions were fully discussed in the rulemaking on part 1270 (''Human Tissue Intended for Transplantation,'' interim rule (58 FR 65514 and 65517 to 65518, December 14, 1993); ''Human Tissue Intended for Transplantation,'' final rule (62 FR 40429 and 40439 to 40440, July 29, 1997).

Authority for the enforcement of section 361 of the PHS Act is provided for in part under section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a) of the PHS Act, any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year (42 U.S.C. 271(a)). 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 (18 U.S.C. 3559, 3571(b)). Organizations may be fined up to $200,000 per violation not resulting in death and $500,000 per violation resulting in death (18 U.S.C. 3559, 3571(c)). In addition, Federal District Courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act.

A. Inspections (Proposed § 1271.400)

Proposed § 1271.400 addresses the inspectional process. In large part,

inspections of establishments that manufacture human cellular and tissue-based products would be conducted in the same manner as inspections of firms dealing in other FDA-regulated commodities.

Establishments subject to inspection include those that perform any step in the manufacture of human cellular and tissue-based products, including recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. All of these establishments, including any location performing contract services, would be required to permit inspections by an authorized FDA representative at any reasonable time and in a reasonable manner. The FDA representative would determine which areas of the establishment to inspect in order to determine compliance with the provisions of part 1271; these might include, but would not necessarily be limited to, the establishment's facilities, equipment, processes, products, procedures, labeling, and records.

Inspections would be made with or without prior notification and would ordinarily occur during regular business hours. The frequency of inspection would be at the agency's discretion.

The FDA representative would call upon the most responsible person available at the time of inspection of the establishment and could question the personnel of the establishment as the representative deems necessary. The FDA representative could review and copy any records required to be kept under part 1271, and could take photographs or make video tapes. The agency notes that, under the policy expressed in Compliance Policy Guide 7151.02, ''FDA Access to Results of Quality Assurance Program Audits and Inspections,'' the FDA representative would not ordinarily review or copy an establishment's records and reports that result from audits of the establishment's quality program established under proposed § 1271.160, when such audits are conducted according to the establishment's written quality program. This policy is intended to encourage the establishment to conduct quality program audits that are candid and meaningful. The agency would continue to have access to all information required to be maintained under proposed part 1271, such as complaint files, information on product deviations, and information on corrective actions.

At the end of the inspection, if possible violations of the regulations are found, the FDA representative would issue to the most responsible person at the establishment a list of ''Inspectional Observations'' (Form FDA–483), describing the observations of the representative that represent an observed or potential problem with the facility or with the human cellular and tissue-based products. After the report of the FDA representative is reviewed, FDA may issue additional correspondence to the establishment describing the violations to the regulations and requesting appropriate follow-up action.

The public disclosure of records containing the name or other positive identification of donors or recipients of human cellular or tissue-based products would be handled in accordance with FDA's procedures on disclosure of information as set forth in 21 CFR part 20. Under these procedures, FDA takes necessary precautions to protect the privacy of names of donors and recipients prior to public disclosure of records containing identifiers of the donor and recipients. FDA recognizes the sensitive nature of information that would identify a human tissue donor or recipient. FDA may copy records containing identification of the donors or recipients if such records are needed; for example, to document the distribution of potentially infectious human cellular and tissue-based products.

The agency invites additional comments on possible alternative inspection and enforcement provisions that would leverage agency resources, be cost-effective, and achieve the public health goals of the proposed rule. The agency welcomes comments on the advantages and disadvantages of various types of programs, such as joint agency-third party inspectional programs and joint Federal-State inspectional and enforcement programs, as well as any other alternative approach that would help ensure compliance with the proposed rule.

B. Imports (Proposed § 1271.420)

Proposed § 1271.420, which is derived from § 1270.42, is intended to clarify the administrative steps for the importation of human cellular and tissue-based products into the United States. Human cellular and tissue-based products that have been recovered from sources outside the United States can enter the country, and products that have been recovered from sources in the United States and then sent outside the United States for processing can reenter the country, consistent with the provisions of part 1271. All imported human cellular and tissue-based products would be required to be accompanied by appropriate records identifying the donor and the status of donor testing and screening in accordance with the records requirements proposed in the donor-suitability proposed rule.

As with other imports, when a human cellular or tissue-based product is offered for entry, the importer of record must notify the director of the FDA district having jurisdiction over the port of entry through which the product is imported or offered for import. ''Importer of record'' is defined in proposed § 1271.3(tt). The human cellular or tissue-based product offered for import must be held intact, under conditions necessary to maintain product function and integrity, prevent contamination, and prevent transmission of communicable disease, until it is released by FDA.

Human cellular and tissue-based products that are offered for import and found to be in violation of part 1271 would be subject to recall and destruction in accordance with § 1271.440.

C. Orders of Retention, Recall, Destruction, and Cessation of Manufacturing (Proposed § 1271.440)

Proposed § 1271.440 describes the procedures for the retention, recall, and destruction of human cellular and tissue-based products and for the cessation of manufacturing operations, and is derived in large part from § 1270.43. Section 1271.440(a) states that, upon a finding that a human cellular or tissue-based product or an establishment is in violation of the regulations in this part (and thus poses a risk of spreading a communicable disease), the agency may issue an order that the product be recalled and/or destroyed, as appropriate, or that it be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or until the safety of the product is confirmed. Alternatively, the agency may take possession of and/or destroy the violative product.

Section 1271.440(c) describes in further detail the order of retention, recall, or destruction, and describes possible alternatives to destruction. Section 1271.440(e) provides an opportunity for a hearing under 21 CFR part 16 and states that, if such a hearing is requested, any possible destruction of human cellular and tissue-based products would be held in abeyance pending resolution of the hearing request.

Proposed § 1271.440(a)(3) contains a provision not found in § 1270.43: an ''order to cease manufacturing until compliance with the regulations of this part has been achieved.'' This type of order would bar an establishment from continuing its manufacturing operations

until the agency has determined that compliance has been achieved. The order will specify the regulations at issue, and will ordinarily specify the particular operations covered by the order (e.g., distribution, labeling, etc.). Operations may not resume without prior authorization of FDA.

Authority for this new provision derives from section 361 of the PHS Act, which states that, ''[f]or purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, * * * destruction * * *, and other measures, as in his judgment may be necessary.'' The agency considers these new measures to be a necessary component of its new comprehensive approach to cell and tissue regulation, which includes the proposed establishment registration and product listing and the proposed CGTP requirements.

The agency recognizes that an order to retain particular human cellular and tissue-based products suspected of being in violation of the regulations may be appropriate in some instances, and intends to continue to issue such orders as necessary. However, such a limited action against a product or products may be an inadequate enforcement tool in some instances; e.g., when an establishment fails to comply with CGTP. In that situation, it may be more appropriate to take action directly against the establishment, rather than against the products of the establishment.

For example, an order to cease operations would be appropriate in the case of an establishment that failed to establish and maintain proper procedures under proposed § 1271.260(a) for storage of human cellular and tissue-based products in such a way as to prevent their cross-contamination. Such a failure to comply with CGTP would cause potential serious communicable-disease risk from all of the establishment's products. An order to retain or destroy particular products would not prevent the establishment from continuing its faulty practices and could therefore be inadequate.

The agency expects that, typically, an order of cessation may be directed only at the distribution of human cellular or tissue-based products and would not affect the rest of an establishment's operations. However, in some cases, the order might cover a particular step in the manufacturing process. And in egregious cases involving serious CGTP deficiencies, the order might cover all of a firm's operations.

V. Proposed Revocation of Part 1270

Part 1270 contains regulations governing infectious disease testing, donor screening, recordkeeping, and enforcement for human tissue intended for transplantation. Products currently subject to the provisions in part 1270 would be considered human cellular and tissue-based products under the definition in § 1271.3(e) and would be regulated under proposed part 1271. The agency has previously announced its intention that proposed part 1271 would supersede the regulations in part 1270 (donor suitability proposed rule (64 FR 52696)). After the regulations in part 1271 go into effect, the regulations in part 1270 will be unnecessary, confusing, and duplicative. For these reasons, the agency now proposes to revoke part 1270.

VI. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 180 days after the date of its publication in the **Federal Register**.

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

VIII. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (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 Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. The Unfunded Mandates Reform Act requires that agencies prepare a written statement under section 202 (a) of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

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 the final rule is a significant regulatory action as defined by the Executive Order and so is subject to review. Because the rule does not impose mandates on State, local, or tribal governments, or the private sector, that will result in an expenditure in any one year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act. Many of the establishments within the tissue industry would be classified as small business entities, and a number of these facilities will incur new costs. Because of the limits of information to characterize the current quality management practices at many of these facilities, and thus the increased effort required to meet the standards of CGTP, the cost impact on small business entities is uncertain. The FDA has therefore prepared an Initial Regulatory Flexibility Analysis.

A. Estimated Cost Impact

With the proposed CGTP rule, the FDA is furthering completion of the set of proposals that represent a comprehensive new system of regulating human cellular and tissue-based products. Manufacturers of tissue products may need to make certain changes to their operations to comply with the rule, such as creating new procedures and providing additional documentation. The proposed rule affects several industries involved in the manufacture of human cellular and tissue-based products. These include: Eye banks, conventional tissue banks, hematopoietic stem cell facilities, and reproductive tissue facilities.

FDA estimates are based on available administrative data on the number of facilities within each industry sector and the number accredited by various industry associations. Where good statistical data are not available, FDA's cost impact estimates have incorporated the quantified judgments of individual experts identified through contacts with the industry associations. Because of the lack of comprehensive data to characterize patterns of current practice within each affected industry sector, and the importance of this data in development of an accurate assessment of cost impact, FDA requests detailed industry comment on the number of facilities involved in the manufacture of cellular and tissue products, and the net change in quality assurance efforts

needed for those facilities to comply with the proposed rule.

1. The Number and Type of Entities Affected

The economic impact of the proposed rule is organized around four subgroups: eye banks, conventional tissue banks, stem cell facilities, and reproductive tissue facilities. The number of facilities and the percent of facilities that follow current industry standards are summarized in table 1 of this document. In estimating net new costs for facilities, it is critical to account for facility adherence to current industry standards. In a number of tissue manufacturing sectors the industry standards for many manufacturing operations meet or exceed the specifications in the proposed rule. Facilities following those standards should experience very little impact in complying with FDA-proposed standards.

As presented in table 1 of this document, FDA estimates that there are 114 eye banks currently operating in the United States, although the EBAA believes that the number of banks is declining and may currently be closer to 100. According to EBAA, virtually all operating eye banks currently comply with the industry (EBAA) medical and procedural standards for quality control. For eye banks, the costs associated with following the proposed rule result from additional quality assurance steps and process documentation as specified under the CGTP.

FDA estimates that 110 tissue banks are involved in the manufacture of other conventional tissue, e.g., pericardium, dura mater, heart valves, skin allografts, bone allografts, fascia, tendon, and ligaments (hereafter referred to as ''conventional tissue banks''). Industry sources report that approximately 75 to 80 percent of these facilities currently follow the standards for tissue banking established by the AATB. For these facilities, there will be some additional cost associated with review of the proposed FDA rule and with alignment of their current procedures to FDA's requirements. There may also be some additional recurring cost, where documentation and quality control required under the proposed rule extend beyond current practice. For the remaining 20 to 25 percent of facilities not following the industry standard, the cost of compliance would be somewhat higher. These facilities may need to establish more formal procedures and quality control steps, and may need to devote added staff hours to performing these procedures and processing controls.

Facilities that produce stem cell products from peripheral blood or from umbilical cord blood would also be affected by the proposed rule. FDA finds that available data to estimate the number of peripheral blood stem cell (PBSC) facilities and current practices are quite limited. The actual number of PBSC facilities may range from 200 to 400. Of the estimated total involved in peripheral blood stem cell production, approximately 150 are currently accredited by the AABB and an estimated 130 have applied for accreditation by the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT). Industry sources estimate that approximately 80 of these facilities are seeking dual AABB/FAHCT accreditation, indicating an unduplicated count of approximately 200 PBSC facilities assumed to be accredited by AABB and/or FAHCT. However, the manufacturing practices of non-accredited facilities 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 facilities may be as high as 400[1] (i.e., 200 more than the number estimated to be accredited by AABB or FAHCT), but the number of IBMTR/ABMTR-estimated facilities that actually process peripheral blood (as opposed to bone marrow) is uncertain.

In addition, the proposed rule would apply to facilities involved with reproductive tissue, primarily sperm banks and Assisted Reproduction Technology (ART) facilities. For purposes of this discussion, references to ART facilities include infertility clinics, and andrology and embryology laboratories. The American Society of Reproductive Medicine (ASRM) has a membership of approximately 330 ART facilities. The ASRM also has a 1996 list of approximately 110 sperm banks operating in the United States. Based on conversations with consultants, most commercial sperm banking and most ART facilities currently adhere to industry standards similar to those in the proposed rule. The 20 largest sperm banks are estimated to handle 95 percent of the total volume of product for the industry, and these facilities are believed to follow industry standards that are comparable to the CGTP. According to industry consultants, approximately one-third of the 20 largest sperm banks are accredited by the AATB, and the remaining two-thirds are licensed by State health agencies, including the California Department of Health and the New York Department of Health. Sperm banks are also regulated under the Clinical Laboratory Improvement Amendment (CLIA) of 1988.

Andrology laboratories at ART facilities are also subject to CLIA 1988. The Committee on Laboratory Accreditation (COLA) and the Joint Commission on Accreditation of Health Care Organization (JCAHO), also inspect embryo laboratories for accreditation. The requirements for accreditation by the College of American Pathologists (CAP), which also accredits ART facilities, closely resemble those in the proposed CGTP rule, with a few exceptions. Consultants estimate that as many as 80 percent of ART facilities may currently comply with the CAP requirements.

TABLE 1.—ESTIMATED NUMBER OF FACILITIES THAT FOLLOW INDUSTRY STANDARDS

Affected Industry	Relevant Industry Standards	Percent of Firms Following Industry Standards
Eye Tissue: 100–114 facilities	EBAA[1]	100% facilities estimated compliant
Conventional Tissue: (e.g., pericardium, dura mater, heart valves, skin allograft, bone allograft) 110 facilities	AATB[2]	75–80% facilities estimated compliant
Stem Cells Peripheral Blood (PB): 400 facilities [uncertain]	AABB or FAHCT[3]	85% accredited facilities estimated compliant
Cord Blood (CB): 25 facilities	FAHCT	100% CB facilities compliant

[1]Based on the National Inpatient Sample of hospital discharge data collected by the Agency for Health Care Policy Research (AHCPR) in the Health Care Utilization Project (HCUP), a total of 7,300 stem cell transplants were performed in 1994, the most recent year reported. With the number of stem cell facilities ranging from 400 to 200, this would translate to a range of 18 to 37 transplants per facility per year. Based on the implied volume of product per facility per year, a total of as many as 400 facilities would seem unlikely if the number of transplants in 1994 were representative of the current volume of demand for stem cell products.

TABLE 1.—ESTIMATED NUMBER OF FACILITIES THAT FOLLOW INDUSTRY STANDARDS—Continued

Affected Industry	Relevant Industry Standards	Percent of Firms Following Industry Standards
Reproductive Tissue Sperm Banks: 110 facilities	AATB; CAP[4] accreditation; State Licensed (e.g., NY,CA); CLIA[5]-certified	20% facilities estimated compliant (accounting for 95% of all production)
Reproductive Tissue ART[6] Facilities: 330 facilities	CAP accreditation; State licensed (e.g., NY,CA); ASRM[7] guidelines	approximately 80% facilities estimated compliant

[1]Eye Bank Association of America
[2]American Association of Tissue Banks
[3]Foundation for the Accreditation of Hematopoietic Cell Therapy
[4]College of American Pathologists
[5]Clinical Laboratory Improvement Amendments of 1988
[6]Assisted Reproductive Technology
[7]American Society for Reproductive Medicine

2. Estimated Impact on Industry Facilities

In the sections that follow, the agency considers each of the provisions of the proposed rule its estimated impact on facilities in the identified sectors of the tissue industry. The impact analysis distinguishes expected cost impacts based on both facility size and estimated current adherence with industry standards. As defined by the U.S. Small Business Administration, a small facility has revenues less that $5.0 million.

TABLE 2.—ESTIMATED COST PER FACILITY AND ESTIMATED PERCENTAGE OF FACILITIES THAT WOULD BE AFFECTED BY PROPOSED CURRENT GOOD TISSUE PRACTICES[1]

Section	Title	*Eye Banks*	*Conventional Tissue* (Small/Large)	*Stem Cell Facilities* (Compliant/ noncompliant)	*Sperm Banks*	*ART[2] Facilities* (Small/Large)
1271.150	CURRENT GOOD TISSUE PRACTICE: GENERAL	– –	– –	– –	– –	– –
1271.155	EXEMPTIONS AND ALTERNATIVES	– –	– –	– –	– –	– –
1271.160	ESTABLISHMENT AND MAINTENANCE OF A QUALITY PROGRAM					
(b)(2)	Functions—Procedures for sharing information	$349 (95%)	$698/ $2,004 (23%)	$0/ $698 (0%/ 80%)	$698 (5%)	$698/ $0 (5%/ 0%)
(b)(3)	Functions—Corrective actions	$414 (95%)	$828 (23%)	$0/ $828 (0%/ 80%)	$828 (5%)	$828/ $0 (5%/ 0%)
(b)(7)	Functions—Investigations	$2,022 (95%)	$2,022 (23%)	$0/ $2,022 (0%/ 80%)	$2,022 (5%)	$2,022 /$0 (5%/ 0%)
(d)(1)	Audits—Annual	$414 (95%)	$828/ $1,656 (23%)	$0/ $828 (0%/ 80%)	$828 (5%)	$828/ $1,656 (50%)
(d)(3)	Audits—Report	$138 (95%)	$276 /$552 (23%)	$207 (95%)	$207 (5%)	$207/ $414 (50%)
(e)	Computers—Validate customized software	$2,040 (10%)	$2,040 (10%)	$2,040 (10%)	$2,040 (5%)	$2,040 (5%)
(f)	Procedures—Quality program					
	—Facility with minor deficiencies	$449 (95%)	$449/ $1,159 (23%)	$449 (80%)	$449 (80%)	$449/ $1,159 (80%)
	—Facility with major deficiencies	$2,191 (5%)	$2,191/ $4,359 (5%)	$0/ $2191 (0%/ 5%)	$2,191 (5%)	$2,191/$4,359 (5%)
	—Cost for additional quality control work	$1,236 (95%)	$1,236 (23%)	$1,236 (80%)	$1,236 (80%)	$1,236 (80%)
1271.170	ORGANIZATION AND PERSONNEL					
(b)	Competent performance of functions—Sufficient personnel	– –	$15,560 (23%)	$0/ $15,560 (0%/ 95%)	$15,560 (5%)	$15,560 (5%)
(c)	Training	– –	$2,348/ $3,104 (23%)	$0/ $2,348 (0%/ 95%)	$2,348 (5%)	$2,348/ $0 (5%/ 0%))
(d)	Records—Personnel	– –	– –-	– –	– –	– –
1271.180	PROCEDURES—GENERAL REQUIREMENTS	$8,280 (5%)	$8,280 (23%)	$0/ $8,280 (0%/ 95%)	$8,280 (50%)	$8,280 (50%)
1271.190	FACILITIES					
(a)	General	– –	– –	– –	$14,000 (5%)	$14,000/$28,000 (5%/ 5%)
(b)	Operation-Separation of Operations	– –	– –	$0/$14,000 (0%/ 95%)	14,000 (5%)	$14,000/$28,000 (5%/ 15%)
(b)	General-Separation	– –	– –			

TABLE 2.—ESTIMATED COST PER FACILITY AND ESTIMATED PERCENTAGE OF FACILITIES THAT WOULD BE AFFECTED BY PROPOSED CURRENT GOOD TISSUE PRACTICES[1]—Continued

Section	Title	*Eye Banks*	*Conventional Tissue* (Small/Large)	*Stem Cell Facilities* (Compliant/ noncompliant)	*Sperm Banks*	*ART*[2] *Facilities* (Small/Large)
(c)(3)	Facility cleaning and sanitation—Procedures	$299 (5%)	$299/ $471 (23%)	$299 (95%)	$299 (5%)	$299/ $471 (5%)
(c)(4)	Facility cleaning and sanitation—Records	– –	– –	– –	– –	– –
1271.195	ENVIRONMENTAL CONTROL AND MONITORING					
(a)	General—Procedures for ventilation and air filtration	– –	$299/ $471 (23%)	$299 (95%)	$299 (80%)	$299/ $471 (80%)
(b)	Inspections—Environmental control systems	$1,000 (5%)	– –	$1,000 (50%/ 95%)	$1,000 (20%)	$1,000/$2,000 (20%)
(c)	Records—Environmental control and monitoring activities	$162 (95%)	$162/ $324 (23%)	$162 (95%)	$162 (80%)	$162/ $324 (80%)
1271.200	EQUIPMENT					
(b)	Procedures and schedules—Cleaning, sanitizing, and maintenance	– –	$1,254/ $2,638 (23%)	$0/ $1,254 (0%/ 95%)	$1,343 (90%)	$1,343/$2,261 (90%)
(c)	Calibration of equipment	– –	$1,254/ $2,638 (23%)	$1,254 (95%)	$1,343 (5%)	$1,343/ $2,261(50%)
(d)	Inspections—Routine	$204 (95%)	$408/ $816 (23%)	$204 (95%)	$204 (5%)	$204/ $408 (5%)
(e)	Records—Maintenance, cleaning, sanitizing, and calibrating activities					
	—Keeping records of cleaning and calibration activities	$162 (95%)	$324/ $648 (23%)	$162 (95%)	$162 (5%)	$162/ $324 (5%)
	—Keeping records of the use of each piece of equipment	$648 (95%)	$1,296/ $2,592 (23%)	$1,296 (95%)	$1,296 (100%)	$1,296/$2,592 (100%)
1271.210	SUPPLIES AND REAGENTS					
(a)	Receipt and verification—Procedures	$100 (95%)	$299/ $471 (23%)	$100/ $299 (95%/ 95%)	$299 (5%)	$299/ $471 (80%)
(b)	Reagents—Procedures in-house	– –	$299/ $471 (23%)	$299 (95%)		
(c)(1)	Records—Receipt of supply or reagent	$162 (95%)	$162 / $324 (23%)	$0 / $162 (0%/ 95%)	$162 (5%)	$162 / $324 (5%)
1271.220	PROCESS CONTROLS					
(b)	Processing material—Procedures for the use and removal of damaging processing materials	$299 (95%)	$299/ $471 (23%)	$299 (95%)	$299 (90%)	$299/ $471 (90%)
(d)	In-process monitoring—Procedures	$349 (95%)	$349/ $1,002 (23%)	$698 (95%)	$349 (5%)	$349/ $1,002 (5%)
1271.225	PROCESS CHANGES					
(a)	Procedures—Process changes	$698 (95%)	$698/ $2,004 (23%)	$0 /$698 (0%/ 95%)	$698 (5%)	$698/ $2,004 (90%)
(b)	Change records	$414 (95%)	$414/ $828 (95%)	$414 (95%)	$414 (90%)	$414/ $828 (90%)
1271.230	PROCESS VALIDATION					
(a)	General	$1,570 (95%)	$1,570 (95%)	$1,570 (95%)	– –	– –
(d)	Procedures	$1,396 (95%)	$698 / $2004 (95%)	$698/ $1,396 (95%/ 95%)		
(e)	Changes and deviations—Revalidation	$785 (95%)	$1,570 (95%)	$1,055 (95%)		
1271.250	LABELING CONTROLS—PROCEDURES	$349 (5%)	$349 / $1,002 (5%)	$349 (5%)	$349 (5%)	$349 / $1,002 (5%)
1271.260	STORAGE	– –	– –	– –	– –	– –
1271.265	RECEIPT AND DISTRIBUTION					
(a)(1)	General—Document identification of product	$816 (5%)	$1,632/ $3,264 (5%)	$1,632/ $3,264 (5%)	$1,632 (5%)	$1,632/ $3,264 (5%)

TABLE 2.—ESTIMATED COST PER FACILITY AND ESTIMATED PERCENTAGE OF FACILITIES THAT WOULD BE AFFECTED BY PROPOSED CURRENT GOOD TISSUE PRACTICES[1]—Continued

Section	Title	*Eye Banks*	*Conventional Tissue* (Small/Large)	*Stem Cell Facilities* (Compliant/ noncompliant)	*Sperm Banks*	*ART*[2] *Facilities* (Small/Large)
(b)	Receiving activities—Procedures	– –	$349/ $1,002 (23%)	$698 (95%)	$698 (5%)	$698/ $2,004 (5%)
(c)	Availability for distribution—Procedures	– –	$349/ $1,002 (23%)	$349/ $698 (95%)	$698 (5%)	$698/ $2,004 (5%)
(d)	Packaging—Validation	$1,296 (95%)	$1,296 (95%)	$544 (95%)	$544 (100%)	$544 (100%)
(f)	Return to inventory—Procedures	– –	$299/ $471 (23%)	$0/$399 (0%/ 95%)	$299 (5%)	$299/$471 (100%)
1271.270	RECORDS					
(a)	General	$648 (95%)	$0/ $648 (0%/ 95%)	$648 (95%)	– –	– –
(b)	Records management systems	$2,760 (95%)	$0/ $2,760 (0%/ 95%)	$2,760 (95%)	$2,760 (5%)	$2,760/$5,520 (50%)
(e)	Length of retention	$18 (5%)	$18 (50%/ 95%)	$18 (95%)	$18 (5%)	$18/$36 (5%)
1271.290	TRACKING					
(b)(1)	Method of product tracking-General method	$698 (5%)	$0/ $349 (0%/ 95%)	$349 (95%)	$349 (80%)	$349/ $1,002 (80%)
(e)	Recipient information	$1,632 (5%)	$0/ $3,264 (0%/ 95%)	$3,264 (95%)	– –	– –
(f)	Consignees	$1,380 (5%)	$1,380 (23%)	$1,380 (95%)	$1,380 (80%)	$1,380 (80%)
1271.320	COMPLAINT FILE					
(a)	Procedures	$100 (95%)	$299/ $471 (23%)	$299 (95%)	$299 (5%)	$299/ $471 (5%)
(b)	Complaint file	– –	– –	– –	– –	– –
(c)	Review and evaluation of complaints	$552 (95%)	$552 / $1,104 (23%)	$552 (95%)	$552 (5%)	$552 / $1,104 (5%)
	E—ADDITIONAL REQUIREMENTS FOR ESTABLISHMENTS DESCRIBED IN 1271.10					
1271.350	REPORTING	– –	– –	– –	– –	– –
1271.370	LABELING AND CLAIMS	– –	– –	– –	– –	– –
	F—INSPECTION AND ENFORCEMENT OF ESTABLISHMENTS DESCRIBED IN 1271.10					
1271.400	INSPECTIONS					
(a)	Inspections—General	$708 (100%)	$708 (100%)	$708 (100%)	$708 (100%)	$708 (100%)
1271.420	HUMAN CELLULAR AND TISSUE-BASED PRODUCTS OFFERED FOR IMPORT	– –	– –	– –	– –	– –
1271.440	ORDERS OF RETENTION, RECALL, DESTRUCTION, AND CESSATION OF MANUFACTURING	– –	– –	– –	– –	– –

[1]Only sections estimated to have compliance costs for these industries are shown. No cost is estimated for a section (indicated by a double dash"—") if the background analysis (see a detailed presentation of cost assumptions provided in FDA's *Cost Impacts of the Proposed Current Good Tissue Practices Rule on Eye Banks, Conventional Tissue Banks and Stem Cell Facilities: Background Paper*, April 1999, and in *Cost Impacts of the Proposed Current Good Tissue Practice Rule on Sperm Banks and ART Facilities*, February 1999, prepared by Eastern Research Group, Inc.) shows that the requirements: (1) Do not apply, (2) have no new cost impact, or (3) are met by another section of the proposed rule.
[2]Assisted Reproductive Technology

As indicated by the information in table 2, the impact of the proposed rule varies, depending upon the sector of the tissue industry and the particular provisions of the proposed rule. For many of the proposed provisions, the facility level impact will entail development of new procedures, or revision of existing procedures. The scope and degree of complexity may vary. FDA expects that the staff typically involved in the development and finalization of facility procedures will include technicians, clerical staff, lab supervisors, and the lab director. For purposes of industry-wide estimation, the agency's analysis relies on standardized estimates of the level of effort and cost for establishing procedures. Table 3 summarizes the agency's assumptions, based on input from industry consultants.[2]

[2]A detailed presentation of level of effort and cost assumptions are provided in FDA's ''Cost Impacts of the Proposed Current Good Tissue Practices Rule on Eye Banks, Conventional Tissue Banks and Stem Cell Facilities: Background Paper,'' April 1999, and in ''Cost Impacts of the Proposed Current Good Tissue Practice Rule on Sperm Banks and ART Facilities,'' February 1999, prepared by Eastern Research Group, Inc. These documents will be available on the CBER website.

TABLE 3.—ESTIMATED LEVEL OF EFFORT AND COST PER PROCEDURE REVISED OR PREPARED TO COMPLY WITH THE PROPOSED CURRENT GOOD TISSUE PRACTICE[1]

Size Category	Minor Procedures		Major Procedures	
Small Facility	Revise Existing	Prepare New	Revise Existing	Prepare New
Staff level of effort	2.0 hrs.	6.0 hrs.	8.0 hrs.	16.0 hrs.
Cost	$99.50	$298.50	$349.0	$698.00
Large Facility				
Staff level of effort	4.0 hrs.	12.0 hrs.	27.0 hrs.	54.0 hrs.
Cost	$157.00	$471.00	$1,002.00	$2,004.00

[1]Small facilities are those with revenues less than $5.0 million. The distinction between major and minor procedures is described in the report by Eastern Research Group, Inc.

The analysis of impact is summarized below through a discussion of the proposed rule provisions and expected type and extent of industry impact. The pertinent section of the proposed rule is noted to facilitate reference to the related estimates in table 2.

a. *Section 1271.150—current good tissue practice: general*. The proposed rule would require manufacturers of human cellular and tissue-based products to follow CGTP. Section 1271.150(a) gives an overview of CGTP but does not present specific compliance requirements. The specific requirements are addressed in subsequent sections. Section 1271.150(b) would require that manufacturers ensure compliance on the part of contractors and proposes the establishment that should be responsible for compliance. FDA expects that facilities would use accredited referral laboratories to ensure compliance with the CGTP rule, and therefore new costs would be associated with § 1271.150(b). Section1271.150(c) explains the relationship of the proposed rule to regulations specifically applicable to biological drugs or devices and paragraph (d) defines the term ''where appropriate'' in relation to the rule. Neither § 1271.150(c) nor (d) would generate any costs for this industry because no compliance requirements are specified.

b. *Section 1271.155—exemptions and alternatives*. The proposed rule would allow establishments to request an exemption or alternative from FDA for any of the requirements of the rule. There is currently no basis for predicting industry requests for exemptions or alternatives, or for predicting the effect of these actions on compliance costs. FDA anticipates that very few facilities will consider it appropriate to be exempted from the quality standards specified in the proposed rule.

c. *Section 1271.160—establishment and maintenance of a quality program*. The proposed rule would require that facilities establish and maintain a quality program. The quality program would include: Procedures for each step in the manufacturing process, procedures for exchanging information with other establishments known to have recovered cells from the same donor, corrective action and documentation, training and education of personnel, appropriate monitoring systems, maintenance of records, investigation and documentation of all product deviations, other actions necessary to assure compliance with the quality program; assignment of authority over the quality control program, audits, computer software validation, and other procedures specific to the quality program. A number 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 industries have the appropriate facilities, equipment, and systems to support comprehensive quality management, but only those already estimated to be following industry standards are expected to have comprehensive quality programs in place. Some facilities may need to upgrade their quality program for several of the proposed requirements. These include: Procedures for sharing information, corrective actions, and investigations. Further, some facilities may need to take additional steps to administer corrective actions and conduct investigations, if they currently do so only when major deviations arise.

Although sharing of information is an industry-wide practice, some small facilities, particularly those not following current industry standards, may not have written procedures and reporting forms for this task. FDA estimates that 95 percent of industry eye banks would need to revise a major procedure; 23 percent of other conventional tissue banks, not following the current AATB standard, would need to write a major procedure to comply with this requirement; 80 percent of the peripheral blood stem cell facilities not following the FAHCT or AABB standards would need to prepare a major procedure; and 5 percent of sperm banks and 5 percent of ART facilities would need to prepare a major procedure to address this requirement.

Although FDA anticipates that most industry facilities take steps to administer corrective actions and conduct investigations, some may currently do so only when major deviations arise.

FDA estimates that 95 percent of eye banks, 23 percent of conventional tissue banks, 80 percent of stem cell facilities, and 5 percent of sperm banks and ART facilities, would need to invest additional time. The incremental time for the laboratory director to administer corrective actions and document these activities is estimated to be an additional half-hour per month of laboratory director time at eye banks that already perform this activity to a lesser extent, and an additional hour per month at all other facilities that will be newly affected by this provision. As shown in table 2 in § 1271.160(b)(7) of the background papers prepared by FDA and Eastern Research Group Inc., (ERG) for newly required investigations in tissue facilities, FDA estimates an additional cost per year of $2,022 for an additional 2 hours per month for the laboratory director to investigate and document deviations, and an additional half hour each for the laboratory supervisor and technician to participate in the investigations.

A number of facilities would also institute other requirements of the quality program, including audits, computer software validation, and procedures specific to the quality program. Audits are part of the industry standards published by the AATB, the EBAA, by FAHCT and the AABB. However, some facilities following these standards may need to do some additional recordkeeping, and facilities not following standards would begin to conduct audits. Referring to table 2, FDA assumes that up to 95 percent of eye banks would increase their audit efforts, including additional lab director time to perform the audit and additional

hours of preparation for the annual audit. An estimated 23 percent of conventional tissue banks, and an estimated 50 percent of ART facilities, would allocate additional resources for annual audits, with a higher allocation of hours at larger facilities, to prepare for, and to conduct the audit. For stem cell facilities, FDA estimates that there would be no additional auditing required at facilities following FAHCT or AABB standards, but an estimated 80 percent of facilities not following industry standards would need to spend additional time to prepare for and to conduct an audit each year. It is also assumed that approximately 5 percent of sperm banks would allocate additional staff hours for these audit-related activities.

In addition to performing the annual audit, the proposed rule would require preparation of an annual audit report. Facilities following current industry standards may need to increase the time for reporting.

FDA estimates that 95 percent of industry eye banks will experience an increase of approximately 2 hours per year of lab director time for preparing the audit report. The 23 percent of conventional tissue facilities not following AATB standards are estimated to devote 4 hours of lab director time, in the case of small facilities, and 8 additional hours of lab director time at large facilities for the preparation of an annual audit report. Laboratory directors of 95 percent of the stem cell facilities, 5 percent of sperm banks, and 33 percent of ART facilities, would spend an estimated additional 3 hours to prepare the annual audit report. Approximately 17 percent of ART facilities would also be affected, with an increase of approximately 6 hours per year of staff time for audit report preparation.

Section 1271.160 of the proposed rule further stipulates that facilities would be required to validate the computer software used in their operations. The FDA assumes that off-the-shelf commercial software packages for particular applications are already validated by the software vendor, but that a facility's custom software would require complete software validation. FDA assumes that none of the affected facilities currently validate their custom software and that approximately 10 percent of eye, conventional tissue and stem cell facilities, and approximately 5 percent of reproductive tissue facilities have developed custom software that would require full software validation under the proposed rule. While the scope of such work can vary, FDA estimates that the custom software in use has a limited scope of application, and an average of 60 hours of work by the laboratory supervisor would be required to validate custom software at a facility. Detailed presentations of these assumptions are provided in section 2.4.3 of the background reports 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 indicate that facilities have quality systems in place, but that most facilities are not aware of some minor elements that should be included in the 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, and up to 80 percent of stem cell facilities, sperm banks and ART facilities will have minor deficiencies that would require them to revise one minor and one major procedure. In addition, FDA estimates that 5 percent of all eye banks, conventional tissue, reproductive tissue facilities, and industry non-compliant stem cell facilities, may identify major deficiencies, and would need to prepare five minor procedures and one major procedure to address those problems.

The agency further assumes that facilities may generally need to do some additional quality control work to comply with the quality control program requirements in the CGTP rule. Although some tasks would not take any additional time to perform, FDA estimates that one additional hour per month each for the laboratory director and supervisor may be needed. FDA estimates that 95 percent of all eye banks, 23 percent of conventional tissue banks and approximately 80 percent of stem cell facilities and reproductive tissue facilities would allocate this additional staff time.

d. *Section 1271.170—organization and personnel.* The proposed rule would require facilities to employ sufficient personnel with the necessary education and experience to complete their tasks. Personnel would be trained to perform their work adequately. The EBAA, AATB, FAHCT, 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 facilities for eye banking, conventional tissue banking, and stem cell production already follow these practices as proposed. The fraction of facilities in conventional tissue and stem cell manufacturing that do not follow industry standards would incur new costs. Similarly, 5 percent of the facilities in the reproductive tissue industries would incur some new costs associated with hiring staff that meet formal training requirements. The cost of this staffing effort is estimated to be approximately $15,560 per affected facility.

FDA anticipates that the 23 percent of conventional tissue facilities, 95 percent of industry-noncompliant stem cell facilities, 5 percent of sperm banks, and 5 percent of small ART facilities would incur new training costs in complying with the proposed rule. For a small tissue establishment, these costs are estimated to average $2,348. The proposed CGTP would also require that records of personnel qualifications and training be maintained, but because the incremental record keeping is minimal, FDA assumes that the cost to comply with this requirement would be negligible. Detailed presentations of these assumptions are provided in section 2.4.4 of the background reports by FDA and ERG.

e. *Section 1271.180—procedures: general requirements.* The proposed rule would require establishments to keep written procedures for all steps performed during manufacturing of human cellular or tissue-based products, and to perform an annual review. FDA anticipates a negligible incremental cost for most facilities following industry standards, and an additional 120 hours by the laboratory director for facilities not following the current industry standards. FDA estimates that 5 percent of eye banks would need to expand their current review efforts, and that 23 percent of conventional tissue banks, 95 percent of stem cell facilities, and 50 percent of reproductive tissue facilities would incur new costs for an annual review.

f. *Section 1271.190—facilities.* The proposed rule stipulates a number of requirements regarding the construction of facilities, covering size, location, lighting, ventilation, plumbing, drainage, and toilet and washing facilities. The facility would also be required to have properly divided areas for appropriate quality control. Cleaning requirements are also outlined, including requirements for written procedures and schedules for cleaning and documentation of cleaning activities. Based on discussions with industry experts, FDA estimates that nearly all facilities that follow industry standards would not incur new costs under the proposed CGTP rule. However, some establishments that generally adhere to cleaning standards do not have written procedures. FDA

estimates that 5 percent of all eye banks, in addition to 23 percent of the conventional tissue banks, 95 percent of all stem cell facilities, and 5 percent of reproductive tissue facilities would incur the cost of writing a minor procedure for cleaning. The facilities provision of the CGTP also would require that records of cleaning be maintained. This proposed requirement is currently practiced by most facilities, and is expected to have a negligible impact on facilities not following industry standards.

g. *Section 1271.195—environmental control and monitoring*. The proposed rule would require that procedures be written for environmental control and monitoring activities or systems where an environmental condition could have an adverse effect on the human cellular or tissue-based product. The rule also would require that environmental control systems be regularly inspected and that control and monitoring activities be documented. The impact of this provision of the CGTP varies by industry sector. For eye banking, the EBAA standards already contain relevant provisions, however, some additional costs may be incurred for annual inspection of the 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 and certification of equipment. FDA anticipates that the conventional tissue facilities following AATB standards would experience no new costs, but that the remaining 23 percent of facilities would need to prepare a minor procedure to control and monitor ventilation and air filtration.

The current FAHCT and AABB standards do not provide for written procedures for environmental control and monitoring. FDA therefore estimates that 95 percent of all stem cell facilities would need to develop a minor procedure to control and monitor ventilation and air filtration to comply with the CGTP. However, because the industry standards provides for appropriate environmental controls, FDA assumes that some facilities are currently performing control activities. The agency estimates that as many as half of the facilities currently following standards may already be conducting routine inspections of their environmental control equipment. It is assumed that the remaining 50 percent of those facilities, and 95 percent of facilities assumed not to be following industry standards, would incur additional costs to inspect equipment and perform recordkeeping related to environmental control.

The agency also assumes that most reproductive tissue facilities would need to prepare written procedures, and do additional recordkeeping in compliance with the CGTP. FDA estimates that 80 percent of all sperm banks and ART facilities would incur costs to comply with this provision of the proposed rule. FDA also estimates that 20 percent of ART facilities would increase ventilation systems inspection activities. Table 2 provides estimates of cost per facility associated with these efforts.

h. *Section 1271.200—equipment*. The proposed rule stipulates that appropriate equipment be used and any equipment used be validated. Cleaning, maintenance, and calibration of equipment would be performed according to established schedules and procedures; equipment would be regularly inspected for adherence to applicable procedures and schedules; and all such activities would be documented. In addition, facilities would be required to keep records of each use of each piece of equipment, including the identification of each human cellular or tissue-based product manufactured with that piece of equipment.

The standards related to equipment, as specified by AATB, EBAA, FAHCT, and AABB generally address maintenance procedures, and recordkeeping related to maintenance. However, the proposed rule extends beyond the industry standard for EBAA, FAHCT and AABB in the areas of equipment inspection and recordkeeping. FDA therefore estimates that 95 percent of all eye banks would allocate an additional half-hour per month for the laboratory supervisor to inspect equipment, an additional half hour per month of technician time to documenting equipment cleaning and calibration, and two additional hours of technician time per month in recording each use of the equipment.

The estimated 23 percent of conventional tissue facilities that currently do not follow AATB standards would also incur new costs related to equipment quality control. FDA estimates that small facilities would prepare one minor procedure for calibration, and for cleaning and other maintenance for each of six pieces of equipment. In addition, small facilities 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 recording each use of the equipment. FDA estimates large facilities would write minor procedures for each of eight pieces of equipment, and would 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 the facilities simultaneously preparing multiple procedures related to equipment would 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 to prepare six to eight equipment maintenance procedures at one time.

Stem cell facilities also would be expected to perform some additional work to align current practice with the proposed CGTP requirements. Current FAHCT procedures provide for routine maintenance and calibration of equipment. In addition, the AABB standards recommend that standard operating procedures (SOP's) be established for proper equipment maintenance and monitoring. To further develop procedures to address routine maintenance and recordkeeping under the proposed CGTP, FDA estimates that 95 percent of all stem cell facilities would prepare a minor procedure for calibration of each of six pieces of equipment. In addition to the preparation of procedures, lab personnel would carry out the maintenance work, estimated to require an additional half hour of supervisor time per month in routine inspection of equipment, an additional half hour per month for technicians to document cleaning and calibration work, and an added 4 hours per month of technician time to record each use of equipment. In addition, most stem cell facilities that do not currently follow FAHCT or AABB standards would incur the cost of preparing a minor procedure for cleaning, for sanitizing and for routine maintenance of six pieces of equipment.

In the reproductive tissue industry, the agency estimates that all facilities have the appropriate equipment to process the tissue products, but that only a small percentage currently conduct recordkeeping and have written procedures related to maintenance, calibration and other activities as specified under the proposed CGTP. The agency estimates that 90 percent of sperm banks and ART facilities would develop additional procedures, and that 100 percent of these facilities would need to perform additional

recordkeeping related to equipment use. In addition, an estimated 5 percent of sperm banks, and 50 percent of ART facilities would devote additional resources to routine calibration of equipment. An estimated 5 percent of facilities would need to also increase efforts in routine inspection, and record keeping related to equipment cleaning and maintenance. The costs per facility associated with each of these areas of activity are presented in table 2. Section 2.4.8 of the ERG background paper provides a detailed presentation of these assumptions.

i. *Section 1271.210—supplies and reagents*. The proposed rule would require that procedures be established for receipt of supplies and reagents used in the manufacture of human cellular and tissue-based products. In particular, manufacturers would be required to verify that supplies and reagents meet specifications designed to prevent transmission of communicable disease and impairment of product function and integrity. Verification of supply or reagent quality could be accomplished with a certificate of analysis. The proposed rule would also require documentation of receipt, verification, and each use of a supply or reagent in product processing.

The existing industry standards address some or all of these activities, and the estimated impact per facility varies accordingly. EBAA standards specify that sterilized supplies and reagents should contain sterilization dates, method or appropriate expiration dates. However, the agency estimates that up to 95 percent of eye banks would be required to develop additional procedures related to receipt and verification, and would devote additional staff time to recording the receipt of supplies and reagents. Similarly, FAHCT 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 stem cell facilities may be required to expand on their current SOP's and recordkeeping in order to comply with the CGTP provisions.

The current AATB standards address most of the requirements for supplies and reagents included in the proposed rule. FDA assumes that the estimated 23 percent of facilities that follow these standards would be required to prepare additional procedures for in-house reagent verification, for receipt and verification, and would devote additional staff time to keeping records of the receipt of supplies and reagents.

Based on consultant estimates that 95 percent of commercial sperm banks follow AATB guidelines, the agency estimates that only 5 percent of sperm banks and 80 percent of ART facilities would need to take new steps to comply with this proposed CGTP provision. For these facilities, the agency anticipates that each facility would need to prepare new procedures for receipt and verification of supplies and reagents, and each will devote additional staff time to recording the receipt of these materials. The estimated costs per facility are presented in table 2.

j. *Section 1271.220—process controls*. The proposed rule would require facilities to monitor manufacturing processes to ensure that specified requirements for the product are met. This includes having written procedures for the use and removal of processing material that can damage products, and procedures for in-process monitoring. The standards for tissue banking specified by the AATB include activities to address these process controls, but the EBAA, FAHCT, and AABB standards do not include specific requirements for monitoring and removal of processing material that may damage the product. FDA estimates that 95 percent of eye banks, 23 percent of conventional tissue banks, 95 percent of stem cell facilities, and 90 percent of sperm banks and ART facilities would need to prepare a minor procedure related to monitoring and removal of damaging processing material. Consultants estimate that most reproductive tissue facilities have procedures for in-process monitoring, and in these industries, an estimated 5 percent of reproductive tissue facilities would need to prepare procedures to address this activity.

k. *Section 1271.225—process changes*. The proposed regulation would require establishments to institute process change procedures that will govern modifications to established operations. Changes to processes would be documented with the date of the change, the date of implementation, the rationale for the change, and appropriate approval signatures. The current standards for AATB, FAHCT and the AABB provide for SOP's for process changes, although recordkeeping procedures are not specified. Current EBAA standards do not provide for SOP's for process changes. FDA therefore estimates that nearly all eye banks would be required to prepare a major procedure for process changes, and would allocate an additional half hour of lab director time to document process changes.

FDA anticipates that conventional tissue banks not following the AATB standard would need to prepare a major procedure related to process changes, and nearly all tissue banks would increase related recordkeeping. The agency estimates that small conventional tissue banks would spend an additional half hour per month of lab director time to document process changes, and large facilities would allocate an additional hour of lab director time for this. FDA anticipates that almost all stem cell facilities that do not follow FAHCT or AABB standards would need to prepare a major procedure to address process changes. In addition, FDA estimates that 95 percent of all stem cell facilities would allocate an additional half hour of laboratory director time to document process changes.

According to industry contacts, most sperm banks already have established written procedures for process changes, and would therefore be in compliance with this proposed provision. FDA is also informed that ART facilities follow standards for process changes, but the procedures may not be in writing. In addition, industry consultants estimate that many reproductive tissue facilities may not keep written records of their process changes. Based on these characterizations, FDA estimates that approximately 5 percent of sperm banks and 90 percent of ART facilities would need to develop a written procedure for process changes. In addition, the agency estimates that 90 percent of sperm banks and ART facilities would need to allocate additional staff time (an estimated one half-hour per month at small facilities and one hour per month at large facilities) to record changes. The associated costs per facility are presented in table 2.

l. *Section 1271.230—process validation*. The proposed rule would require facilities to validate processes that cannot be verified through subsequent inspection and testing. Current EBAA standards do not require process validation. Although current AATB, FAHCT, and AABB standards include provisions for process validation and related recordkeeping, industry experts indicate that additional validation work would be required at nearly all facilities under the proposed rule. FDA therefore estimates that 95 percent of all eye banks, of all conventional tissue banks and all stem cell facilities, not compliant with AABB or FAHCT, would need to prepare two major procedures related to process validation, and 95 percent of conventional tissue banks and AABB/FAHCT-compliant stem cell facilities

would need to revise two major procedures. FDA estimates that 95 percent of all facilities in the tissue industry would devote additional staff time for process validation.

In addition to the initial validation work, CGTP would require revalidation of procedures. The agency estimates that 95 percent of eye banks, conventional tissue banks and stem cell facilities would need to allocate an additional amount (on the order of 20 to 40 hours) of laboratory staff time for annual revalidation.

Reproductive tissue industry consultants considered that the process validation requirement would have limited application to this industry because the tissues involved in laboratory processes (e.g., sperm and ova) are not uniform in quality. However, quality control through in-process monitoring (under § 1271.220) would be applicable to these tissues.

m. *Section 1271.250—labeling controls: procedures*. The proposed rule would require facilities to establish and maintain written procedures for controlling the labeling of products. The procedures would ensure proper identification of products and include various checks and verifications. Each product would also be accompanied by donor suitability information, if applicable. Other labeling requirements would also be met, such as labeling products appropriately with the required information.

According to consultants and industry contacts, labeling controls are usual and customary practice in the industry. FDA anticipates that only about 5 percent of all facilities in eye banking, in conventional tissue banking, in stem cell processing and in the reproductive tissue industries would need to do additional work to comply with the proposed labeling controls. FDA estimates that such facility would need to revise a major procedure for proper identification of products.

n. *Section 1271.260—storage*. The proposed rule would require that storage areas be controlled to prevent mix-ups and contamination. Temperature should be monitored and limits established, including expiration dating where appropriate. Each of the relevant industry standards contains provisions regarding storage practices. Based on agency review of current industry standards, and conversations with experts about current practices at facilities, FDA anticipates that virtually all facilities follow industry standards that would comply with this provision of the proposed CGTP. These provisions of the proposed rule are therefore expected to produce no new cost impact for facilities in eye banking, conventional tissue banking, stem cell processing, and reproductive tissue.

o. *Section 1271.265—receipt and distribution*. The proposed rule would require that procedures be established and maintained for receiving, rejecting, distributing, and disposing of human cellular or tissue-based products. Documentation of each of those activities, when performed, would also be required. Packaging and shipping containers would be validated and appropriate shipping conditions must be defined. Procedures would 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 provisions related to this area of quality control, except for package validation, are included in each of the relevant standards.

The primary impact of the proposed CGTP provisions for product receipt and distribution thus involves packaging validation for most facilities, and procedures development for facilities that do not currently follow industry standards. FDA estimates that 95 percent of eye banks, conventional tissue banks and stem cell facilities would allocate approximately 4 extra hours per month for a laboratory technician to validate packaging, particularly packaging changes. In addition, an estimated 5 percent of eye banks, conventional tissue banks, and stem cell facilities would increase lab supervisor time to document receipt of products.

The agency estimates that conventional tissue banks not following AATB standards would 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 stem cell facilities would need to write one major procedure addressing receiving activities. Facilities following FAHCT or AABB standards would also need to revise a major procedure for product distribution, while all other facilities would need to prepare a new major procedure for product distribution as well as a minor procedure for handling of products returned to inventory.

According to industry contacts, most sperm banks and ART facilities have a protocol for receiving and distributing reproductive tissue products, however, an estimated 5 percent of facilities would need to write a major procedure for receiving activities and one for distribution. Similarly, an estimated 5 percent of facilities do not currently follow industry standards for product documentation. The agency estimates that an additional 4 to 8 hours of staff time per month would be required by those facilities, for documentation activities. Industry consultants indicate that although most reproductive tissue facilities utilize ''dry shippers'' for shipped products, most do not perform formal packaging validation. FDA therefore estimates that all facilities would be required to perform packaging validation, in compliance with the proposed CGTP. Experts in the reproductive tissue industry also consider it unusual for a product to be returned to inventory; given the potential risk of product deterioration or damage. It is expected that most sperm banks already have a formal procedure for handling returned product, and that ART facilities generally have an established protocol, but not a written procedure. The agency estimates that approximately 5 percent of sperm banks and 100 percent of ART facilities therefore would be required to write a minor procedure to comply with this proposed CGTP requirement. The costs per facility for these activities are presented in table 2.

p. *Section 1271.270—records*. The proposed rule would require that records be maintained for any significant step in the manufacturing process. A records management system would need to be in place and procedures would need to be established for keeping records associated with donor suitability record keeping requirements. Records would be maintained for at least 10 years. The proposed rule would also require that records be kept of any contracts or agreements. Although many components of the required recordkeeping system are addressed under separate provisions of the proposed CGTP, there may be a few minor gaps in the records system of a facility that would be addressed under this general provision. FDA therefore estimates that approximately 95 percent of all eye banks, conventional tissue banks, and stem cell facilities that follow FAHCT or AABB standards, would be required to write at least one minor procedure, and revise one major procedure related to recordkeeping.

The agency also estimates that additional lab director time would be allocated (estimated 40 hours at small facilities and 80 at large facilities) to set up enhanced recordkeeping where a system is already in place. System enhancement would be performed at an estimated 95 percent of eye banks, 23 percent of conventional tissue facilities,

95 percent of stem cell facilities, 5 percent of sperm banks, and 50 percent of the ART facilities.

Various industry standards specify record retention, although the time periods vary somewhat. Of those facilities following industry standards, approximately 95 percent of eye banks and the 77 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 facilities, and the stem cell facilities that do not currently follow industry standards, FDA estimates increased record retention costs based on the cost of storing an additional 5 boxes (2.4 cubic feet each) of records per year for 5 years. The retention standards of FAHCT and AABB for records related to products are different from those concerned with facility and equipment maintenance and personnel training. All records related to the product should be retained indefinitely and records related to facility and equipment maintenance and personnel training should be retained for only 5 years.

FDA estimates that a half of the records at stem cell facilities following industry standards would need to be retained for an additional 5 years, and the annual cost will be comparable to that of other small tissue facilities. The agency also estimates that nearly all stem cell facilities that are not following industry standards will increase record retention. Almost all stem cell facilities that do not follow industry standards would be required to prepare at least one minor procedure and to revise a major procedure related to record keeping. The laboratory director at these facilities would be expected to allocate 40 hours of time to improving the facility's current recordkeeping system.

Consultants estimate that within the reproductive tissue industries all facilities have some record management system, and many facilities have systems that meet the requirements of the proposed rule. Consultants estimate that most sperm banks and the currently accredited ART facilities have adequate records management systems in place, but that approximately 5 percent of sperm banks, and about 50 percent of the ART facilities would need to allocate additional laboratory staff time (i.e., 40 hours at small facilities and 80 hours at larger facilities) to enhance their current recordkeeping system in compliance with the proposed rule.

In addition, FDA is informed that the usual and customary practice in most ART facilities is to retain donor records for an indefinite period. Usual and customary practice in sperm banks is to retain records for at least 15 years, thus more than the 10-year period specified in the proposed rule. It is estimated that only 5 percent of sperm banks and ART facilities would need to extend record retention by an estimated 5 years. The additional cost of storing these files is based on an assumption of 5 boxes (each approximately 2 cubic feet) accumulated per year at small facilities, and 10 boxes per year at large facilities, for an additional 5 years, at a cost of 30 cents per cubic foot per year. The estimated costs per affected facility are summarized in table 2.

q. *Section 1271.290—tracking.* The proposed rule stipulates the steps needed to properly track a product from donor to recipient and vice versa. The proposed CGTP would require that facilities maintain a method for product tracking and that each product be assigned and labeled with a unique identifier. If a new identifier is assigned during the manufacturing process, procedures would be required for relating the new identifier to the old identifier. Records of product transfers would be kept in the recipient's medical records. The facility that manufactured the product would also keep track of the disposition of each product, so that the recipient of the product can be easily identified. Facilities would be required to inform consignees of the established tracking method and would be required to document that consignees agreed to participate in their tracking method.

Product ''traceability'' is a familiar concept and common practice in eye banking, in conventional tissue banking, and in the stem cell processing industry. 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 facilities would need to enhance current tracking, and would be required to prepare one major procedure related to product tracking, spend additional staff time each month to identify and document recipient information, and would allocate additional laboratory director time to institute agreements for information sharing with the consignees who will receive products.

Conventional tissue facilities following AATB standards are able to trace all products from donation source to product recipient. Conventional tissue facilities not following AATB requirements would be required to revise a major procedure to address product tracking, allocate additional staff time each month to obtain and record information about product recipients, and allocate some additional laboratory director time (on a one-time basis) to institute formal contracts with consignees. The FAHCT and AABB standards for product tracking in stem cell facilities recommend that the facility 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 stem cell facilities would, on a one-time basis, allocate an additional 20 hours of laboratory supervisor time to institute agreements for information sharing with the consignees who will receive products. In addition, FDA estimates that 95 percent of stem cell facilities that are not following FAHCT or AABB standards would need to revise a major procedure related to product tracking, and would need to allocate additional staff hours each month for recipient identification and documentation.

Consultants for the reproductive tissue industry indicate that although sperm banks and ART facilities generally perform product tracking and adhere to the practice of documenting recipient information for products, current practices in assigning and documenting products with unique identifiers throughout tissue processing may widely vary, and there may be little documentation of tracking agreements with consignees. Most reproductive tissue facilities therefore would need to review current systems and perform some enhancements. It is estimated that 80 percent of reproductive tissue facilities would need to revise a major procedure related to product tracking, and would allocate additional staff hours each month for recipient identification and documentation. In addition, approximately 80 percent of facilities would need to allocate lab supervisor time to institute agreements for information sharing with the consignees who will receive products. The estimated cost per facility to perform these activities are presented in table 2.

Hospitals generally handle all categories of cellular and tissue-based products. For accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), organizations that store tissue must keep records that permit tracing of any tissue from the donor or source facility to all recipients or other final dispositions. The records must include documentation of tissue use in the patient's clinical record. Most hospitals are accredited and, therefore, are presumed to be tracking tissue to recipient. We believe that hospitals not accredited tend to be specialized

facilities not handling cellular and tissue-based products. Because we know of no hospital receiving tissues and not currently tracking tissue to recipient, we expect hospitals to incur no additional costs as a result of this regulation. However, as some of our sources (Ref. 45) lack conclusive data on the adequacy of hospital recordkeeping, we welcome comment on this matter.

The proposed rule would also require that specimens of dura mater be archived for the appropriate duration under appropriate conditions to enable future testing for evidence of TSE. FDA recommends that the specimens be archived for 16 years beyond the expiration date. As CDRH guidance already recommends that such specimens be archived for 10 years, this requirement would not impose an additional tracking burden. FDA assumes the incremental cost of the longer storage time to be extremely small and the overall cost impact to be negligible.

r. *Section 1271.320—complaint file*. The proposed rule would require facilities to maintain procedures for reviewing and evaluating complaints and to maintain a file for these complaints. Facilities would be required to review and evaluate complaints and to determine whether each complaint represents an event that should be reported to FDA. Documentation of the review and evaluation would be required, even if no investigation is made. FDA finds that the AATB, FAHCT, and AABB standards explicitly address procedures or recordkeeping related to complaints. Based on discussions with industry experts, the agency assumes that nearly all facilities currently track, albeit informally, the complaints received from consignees and recipients. Facilities that would be required to prepare written procedures for handling complaints, and to review complaints on a yearly basis, would incur additional costs. The agency estimates that additional costs for facilities to maintain a complaint file would be negligible.

To fully comply with provisions in the proposed rule, FDA estimates that 95 percent of all eye banks would revise a minor procedure to include the required handling of complaints, and would allocate some additional staff time each year to review complaints. FDA assumes that conventional tissue facilities following AATB standards would already perform the necessary activities, but the estimated 23 percent of facilities not following AATB standards would need to prepare a minor procedure for complaint handling, and would allocate additional laboratory director time each year to review complaints that are received.

Although the industry standards for stem cell processing provide that records be maintained of both donor and recipient complaints, the proposed rule requires that facilities also have written procedures for complaint review. FDA therefore estimates that 95 percent of all stem cell facilities would be required to write a minor procedure to handle complaints, and that 95 percent of all facilities would also be required to allocate additional time for yearly review and handling of complaints.

Consultants assessing the impact of the proposed rule on the reproductive tissue industry estimate that about 95 percent of sperm banks and ART facilities already have written procedures for dealing with complaints, and that 5 percent of facilities would need to prepare a minor procedure for complaint handling, and would allocate additional laboratory director time each year to review complaints that are received. The estimated costs per affected facility are presented in table 2.

s. *Section 1271.350—reporting*. The proposed rule would require facilities to review adverse reaction reports and report any adverse reactions, or product deviations, involving transmission of disease, or of the failure of a product that is fatal, life-threatening, results in permanent impairment of the body, or requires surgical intervention. Based on expert assessments of current industry practices, and the inclusion of adverse event reporting in current industry standards, the agency expects that this requirement, within the proposed CGTP framework for quality management, would impose a negligible cost on facilities in the industry.

t. *Section 1271.370—labeling and claims*. The proposed rule would require that products be labeled clearly and accurately, with information including name and address of the manufacturer, a description of the product, and product expiration date. The storage temperature, warnings, and instructions would be required on the label or on a package insert. The rule would also require that any claims on labeling be truthful and that any therapeutic claim or claim of a clinical outcome of a product would be subject to regulation under section 351 of the PHS Act and/or the act.

Industry consultants inform FDA that such elements are typically present on the labels of products manufactured by eye banks, conventional tissue banks, stem cell facilities, sperm banks and ART facilities. Proper labeling is considered very important to these industries, to prevent misuse of the product. In addition, these industries generally do not make therapeutic or related claims for their products. FDA assumes, therefore, that the industry would be in compliance with this provision of the proposed CGTP rule, and estimates that the cost impact would be negligible.

u. *Section 1271.400—inspections*. FDA could conduct inspections of any facility subject to the proposed CGTP rule. FDA would 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 the proposed rule. The agency estimates that all industry facilities would be subject to this provision of the proposed CGTP, and that inspections would occur annually. FDA estimates that up to 16 hours of laboratory technician time could 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 would be needed for activities related to the inspection. This is expected to yield a cost of approximately $702 per facility.

v. *Section 1271.420—human cellular and tissue-based products offered for import*. The proposed rule would require importers of human cellular and tissue-based products to notify the FDA district director having jurisdiction over the port of entry through which the product is imported or offered for import. The product would be held intact until it is inspected and released by FDA.

In the cellular and tissue-based product industries there is currently very little use of imported tissue that would trigger activities for facility compliance with this provision of the proposed CGTP. FDA therefore estimates the current cost for industry compliance with this proposed requirement would be negligible.

w. *Section 1271.440—orders of retention, recall, and cessation of manufacturing*. Industry firms could incur costs to comply with orders under this proposed provision. There is little available data on which to base estimates of the future frequency and scope of tissue industry conditions and practices that would necessitate such actions on the part of FDA. The agency anticipates that product orders under this provision would be rare. FDA estimates that the yearly costs to

industry resulting from such orders would therefore be negligible.

3. Summary of One-Time and Yearly Cost Impacts

The costs for each subsection of the proposed rule are the product of the estimated number of affected establishments in the industry (table 1), the establishment noncompliance rate by CGTP provision, by industry sector, and the compliance cost per establishment (table 2). Total compliance costs, summed by provision of the proposed rule, are presented by sector in tables 4 through 8. The aggregate compliance costs for all tissue industries are summarized in table 9. The total annualized costs presented in these summary tables include the reported one-time costs, such as are incurred to prepare new procedures, annualized over 10 years using a 7 percent discount rate.

TABLE 4.—AGGREGATE COMPLIANCE COSTS FOR EYE BANKS

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.150	Current good tissue practice: general	$0	$0	$0
1271.155	Exemptions and alternatives	$0	$0	$0
1271.160	Establishment and maintenance of a quality program	$122,111	$457,459	$474,845
1271.170	Organization and personnel	$0	$0	$0
1271.180	Procedures—General requirements	$0	$47,196	$47,196
1271.190	Facilities	$1,701	$0	$242
1271.195	Environmental control and monitoring	$0	$23,245	$23,245
1271.200	Equipment	$0	$109,816	$109,816
1271.210	Supplies and reagents	$10,776	$17,545	$19,079
1271.220	Process Controls	$70,124	$0	$9,984
1271.225	Process changes	$75,593	$44,836	$55,599
1271.230	Process validation	$321,218	$85,016	$130,750
1271.250	Labelling Controls—Procedures	$1,989	$0	$283
1271.260	Storage	$0	$0	$0
1271.265	Receipt and distribution	$0	$145,008	$145,008
1271.270	Records	$369,032	$103	$52,644
1271.290	Tracking	$11,845	$9,302	$10,989
1271.320	Complaint file	$10,776	$59,782	$61,316
1271.350	Reporting	$0	$0	$0
1271.370	Labelling and claims	$0	$0	$0
1271.400	Inspections	$0	$80,712	$80,712
1271.420	Human cellular and tissue-based products offered for import	$0	$0	$0
1271.440	Orders of retention, recall, destruction, and cessation of manufacturing	$0	$0	$0
Total		$995,165	$1,080,020	$1,221,708

TABLE 5.—AGGREGATE COMPLIANCE COSTS FOR CONVENTIONAL TISSUE FACILITIES

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.150	Current good tissue practice: general	$0	$0	$0
1271.155	Exemptions and alternatives	$0	$0	$0
1271.160	Establishment and maintenance of a quality program	$77,800	$137,655	$148,732
1271.170	Organization and personnel	$393,668	$63,751	$119,801
1271.180	Procedures—General requirements	$0	$209,484	$209,484
1271.190	Facilities	$8,544	$0	$1,216
1271.195	Environmental control and monitoring	$8,544	$5,030	$6,247
1271.200	Equipment	$79,352	$62,969	$74,267
1271.210	Supplies and reagents	$17,088	$5,030	$7,463
1271.220	Process Controls	$21,128	$0	$3,008
1271.225	Process changes	$25,169	$53,096	$56,679
1271.230	Process validation	$268,024	$164,065	$202,226
1271.250	Labelling Controls—Procedures	$2,736	$0	$390
1271.260	Storage	$0	$0	$0
1271.265	Receipt and distribution	$33,713	$146,448	$151,248
1271.270	Records	$172,967	$455	$25,082
1271.290	Tracking	$47,498	$101,347	$108,110
1271.320	Complaint file	$8,544	$17,140	$18,356

TABLE 5.—AGGREGATE COMPLIANCE COSTS FOR CONVENTIONAL TISSUE FACILITIES—Continued

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.350	Reporting	$0	$0	$0
1271.370	Labelling and claims	$0	$0	$0
1271.400	Inspections	$0	$77,880	$77,880
1271.420	Human cellular and tissue-based products offered for import	$0	$0	$0
1271.440	Orders of retention, recall, destruction, and cessation of manufacturing	$0	$0	$0
Total		$1,164,775	$1,044,350	$1,210,189

TABLE 6.—AGGREGATE COMPLIANCE COSTS FOR STEM CELL INDUSTRIES

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.150	Current good tissue practice: general	$0	$0	$0
1271.155	Exemptions and alternatives	$0	$0	$0
1271.160	Establishment and maintenance of a quality program	$188,166	$473,119	$499,909
1271.170	Organization and personnel	$739,100	$111,530	$216,761
1271.180	Procedure—General requirements	$0	$393,300	$393,300
1271.190	Facilities	77,983	$665,000	$676,103
1271.195	Environmental control and monitoring	$77,983	$202,323	$213,426
1271.200	Equipment	$387,080	$434,198	$489,309
1271.210	Supplies and reagents	$113,430	$7,695	$23,845
1271.220	Process Controls	$260,336	$0	$37,066
1271.225	Process changes	$33,155	$108,158	$112,878
1271.230	Process validation	$625,670	$275,619	$364,700
1271.250	Labeling Controls—Procedures	$4,799	$0	$683
1271.260	Storage	$0	$0	$0
1271.265	Receipt and distribution	$446,405	$26,520	$90,078
1271.270	Records	$161,856	$2,880	$25,925
1271.290	Tracking	$377,103	$155,040	$208,731
1271.320	Complaint file	$77,983	$144,210	$155,313
1271.350	Reporting	$0	$0	$0
1271.370	Labeling and claims	$0	$0	$0
1271.400	Inspections	$0	$194,700	$194,700
1271.420	Human cellular and tissue-based products offered for import	$0	$0	$0
1271.440	Orders of retention, recall, destruction, and cessation of manufacturing	$0	$0	$0
Total		$3,571,049	$3,194,292	$3,702,727

TABLE 7.—AGGREGATE COMPLIANCE COSTS FOR ART[1] FACILITIES

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.150	Current good tissue practice: general	$0	$0	$0
1271.155	Exemptions and alternatives	$0	$0	$0
1271.160	Establishment and maintenance of a quality program	$272,904	$586,854	$625,709
1271.170	Organization and personnel	$256,740	$25,358	$61,912
1271.180	Procedures—General requirements	$0	$1,366,200	$1,366,200
1271.190	Facilities	$5,909	$621,600	$622,441
1271.195	Environmental control and monitoring	$94,536	$146,342	$159,802
1271.200	Equipment	$767,022	$583,549	$692,756
1271.210	Supplies and reagents	$94,536	$3,596	$17,056
1271.220	Process Controls	$115,834	$0	$16,492
1271.225	Process changes	$341,302	$165,434	$214,028
1271.230	Process validation	$0	$0	$0
1271.250	Labeling Controls-Procedures	$9,481	$0	$1,350
1271.260	Storage	$0	$0	$0

TABLE 7.—AGGREGATE COMPLIANCE COSTS FOR ART[1] FACILITIES—Continued

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.265	Receipt and distribution	$335,612	$36,230	$84,014
1271.270	Records	$612,720	$400	$87,637
1271.290	Tracking	$516,010	$0	$73,468
1271.320	Complaint file	$5,909	$12,254	$13,096
1271.350	Reporting	$0	$0	$0
1271.370	Labeling and claims	$0	$0	$0
1271.400	Inspections	$0	$233,640	$233,640
1271.420	Human cellular and tissue-based products offered for import	$0	$0	$0
1271.440	Orders of retention, recall, destruction, and cessation of manufacturing	$0	$0	$0
Total		$3,428,515	$3,781,457	$4,269,601

[1]Assisted Reproductive Technology

TABLE 8.—AGGREGATE COMPLIANCE COSTS FOR SPERM BANKS

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.150	Current good tissue practice: general	$0	$0	$0
1271.155	Exemptions and alternatives	$0	$0	$0
1271.160	Establishment and maintenance of a quality program	$12,105	$23,661	$25,384
1271.170	Organization and personnel	$15,560	$2,348	$4,563
1271.180	Procedures-General requirements	$0	$82,800	$82,800
1271.190	Facilities	$299	$28,000	$28,042
1271.195	Environmental control and monitoring	$4,776	$6,592	$7,272
1271.200	Equipment	$25,522	$26,286	$29,920
1271.210	Supplies and reagents	$299	$162	$204
1271.220	Process Controls	$5,722	$0	$815
1271.225	Process changes	$698	$7,452	$7,551
1271.230	Process validation	$0	$0	$0
1271.250	Labeling Controls-Procedures	$349	$0	$50
1271.260	Storage	$0	$0	$0
1271.265	Receipt and distribution	$12,575	$1,632	$3,422
1271.270	Records	$2,760	$18	$411
1271.290	Tracking	$27,664	$0	$3,939
1271.320	Complaint file	$299	$552	$594
1271.350	Reporting	$0	$0	$0
1271.370	Labeling and claims	$0	$0	$0
1271.400	Inspections	$0	$14,160	$14,160
1271.420	Human cellular and tissue-based products offered for import	$0	$0	$0
1271.440	Orders of retention, recall, destruction, and cessation of manufacturing	$0	$0	$0
Total		$108,628	$193,663	$209,127

TABLE 9.—SUMMARY OF AGGREGATE COMPLIANCE COSTS FOR ALL TISSUE INDUSTRIES

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.150	Current good tissue practice: general	$0	$0	$0
1271.155	Exemptions and alternatives	$0	$0	$0
1271.160	Establishment and maintenance of a quality program	$673,085	$1,678,748	$1,774,580
1271.170	Organization and personnel	$1,405,068	$202,987	$403,038
1271.180	Procedures—General requirements	$0	$2,098,980	$2,098,980
1271.190	Facilities	$94,435	$1,314,600	$1,328,046
1271.195	Environmental control and monitoring	$185,839	$383,532	$409,991
1271.200	Equipment	$1,258,976	$1,216,819	$1,396,069
1271.210	Supplies and reagents	$236,129	$34,028	$67,648

TABLE 9.—SUMMARY OF AGGREGATE COMPLIANCE COSTS FOR ALL TISSUE INDUSTRIES—Continued

Section	Title	One-Time Costs	Annual Costs	Total Annualized Costs
1271.220	Process Controls	$473,145	$0	$67,365
1271.225	Process changes	$475,917	$378,976	$446,735
1271.230	Process validation	$1,214,911	$524,700	$697,675
1271.250	Labelling Controls—Procedures	$19,354	$0	$2,756
1271.260	Storage	$0	$0	$0
1271.265	Receipt and distribution	$828,305	$355,838	$473,770
1271.270	Records	$1,319,336	$3,856	$191,700
1271.290	Tracking	980,120	265,690	405,237
1271.320	Complaint file	$103,510	$233,937	$248,675
1271.350	Reporting	$0	$0	$0
1271.370	Labelling and claims	$0	$0	$0
1271.400	Inspections	$0	$601,092	$601,092
1271.420	Human cellular and tissue-based products offered for import	$0	$0	$0
1271.440	Orders of retention, recall, destruction, and cessation of manufacturing	$0	$0	$0
Total		$9,268,130	$9,293,783	$10,613,357

B. Estimated Benefits of the Proposed Rule

The overall purpose of the CGTP rule is to prevent the introduction, transmission, or spread of communicable disease through the use of human cellular and tissue-based products. Although industry quality standards exist for most of the affected products, not all members of the industry follow these standards. FDA finds that public safety cannot be assured or effectively protected through reliance on this less formal and voluntary mechanism for quality assurance. The existing industry standards vary to some extent in their comprehensiveness. Moreover, there are variations in the extent to which the industry follows these standards.

For example, most industry consultants for the cost analysis agree that quality standards, such as those proposed by the FDA, and similar standards recommended by industry, could substantially reduce the risk of product contamination and product failure. However, most experts also opined 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 facilities are not currently following adequate quality control standards. A regulatory requirement for quality systems would provide the incentive needed to bring all facilities to a more uniform and appropriately high standard of quality.

The primary beneficiaries of the proposed CGTP rule would be the patients who receive the cellular and tissue-based products. Benefits to patients would result from the reduced risk of communicable disease by avoiding product contamination or product failure through CGTP. The discussion that follows considers the potential benefit of avoided problems with tissue products, based on a survey of the clinical literature.

Recent clinical literature indicates that each type of tissue product considered in the proposed rule has documented contamination or other product problems resulting from processing, or other steps in manufacturing. These reported quality problems provide a basis for assessing the magnitude of the potential benefit from further reducing events that increase the risk of communicable disease transmission. In cases involving eye tissue, conventional tissue, or stem cell products, problems have required medical intervention to treat infection, or to replace an implanted defective product. In some clinical applications, product failures have increased the risk of patient mortality. In other applications, such as embryo processing, poor product quality is associated with lower success rates (i.e., pregnancy rates) among treated patients, which results in an increase in transfer attempts. In general, FDA anticipates that the risk of communicable disease transmission from product quality problems will decline as a result of compliance with the proposed CGTP.

The sections that follow describe product-related problems associated with communicable disease transmission that are at least partly attributable to a lack of uniform quality standards in manufacturing. The costs related to correcting these problems are considered, in order to gauge the potential magnitude of the benefits associated with improved quality in manufacturing. The discussion is organized by types of tissue product.

1. Eye Tissue Products

Primary corneal graft failure is a key adverse outcome of concern following corneal tissue transplant. Such failures result in additional graft attempts. Each attempt increases the risk of communicable disease transmission by exposing the recipient to another tissue product and to 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. 3), donor infectivity (e.g., with Herpes Simplex Virus) (Ref. 4) length of product storage, storage medium, and shipping distance from the eye bank to the recipient site. In a recent analysis of factors contributing to primary corneal graft failure, Wilhelmus et al. found that ''[T]he 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, with modern eye bank screening and preservation procedures, a donor corneal storage time greater than 1 week increases the risk of primary failure by more than twofold.

Wilhelmus et al. include in their analysis a summary of selected findings of studies published between 1971 and

1994 reporting primary graft failure for corneal transplants using 4 °C preservation, and using a variety of preservation methods. The rates of primary graft failure ranged from 0.9 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 documentation of the receipt of supplies and reagents used in tissue processing. The authors found the identical manufacturer's lot number for the preservation medium among 2 media in 34 cases, among 3 media in 36 cases, and among 4 media in 16 cases. Thus, 86 cases (approximately 59 percent of cases) with primary graft failure shared preservation media from the same lots. The lot number was unique in 45 cases (31 percent) and was not recorded in 16 cases (10 percent of cases) involving product failure. These findings also underline the importance of the proposed CGTP-required verification of quality and documentation of each particular lot of processing media used in the manufacture of a uniquely labeled and traceable product.

Primary corneal graft failure typically requires repeat surgery to replace the failed graft. According to the Agency for Health Care Policy Research (AHCPR)[3] (Ref. 5), an estimated 7,443 corneal transplants were performed in 1994, with a mean hospital length of stay (LOS) of 2 days, and a mean total hospital charge equal to $7,530. The estimated rate of primary graft failure resulting from one or more aspects of product collection, processing, or distribution ranges from 0.1 percent (the number of cases officially reported to EBAA for the period 1991 to 1993) 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 the AHCPR-reported 1994 volume of corneal transplants, the estimated cases of primary graft failure may range from 7 cases [0.001 × 7,443] to 156 cases [0.021 × 7,443]. The total cost of replacement of a failed corneal graft is estimated to include $454 of physician services, including an office visit to diagnose the graft failure prior to hospitalization[4] (Ref. 6), and initial and follow-up physician visits during patient hospitalization[5] (Ref. 6) for the repeated corneal transplant. It also includes one follow-up physician office visit to assess the outcome of the second transplant. The patient is estimated to further incur at least one week of time lost from work for the doctor visits, hospitalization and recovery of visual function after surgery. The cost of $772 for this patient time loss is estimated based on a 40-hour work week and average hourly compensation of $19.30.[6] Thus, the current cost impact of corneal graft failure may range from $61,292 [7 × ($7,530 + $454 + $772)] to $1,365,936 [156 × ($7,530 + $454 + $772)].

These estimates provide an indication of the potential cost savings from avoided eye tissue product failures, based on corneal transplants. Tissue quality would improve through the institution of multiple good quality practices, including the validation of processing methods, the verification of processes quality control, and improved documentation. Since these events represent only one type of eye tissue product, the potential for benefit across all products in the eye tissue industry may be greater. The estimated benefits of CGTP applied to eye tissue, measured in terms of avoided corneal graft failures, therefore provide a lower-bound estimate of the potential benefits of the proposed rule. Based on just this one type of eye tissue product, the cost of graft failures that may be avoidable through a universal application of good tissue practices ranges from $61,292 per year, with the lower estimated failure rate, to $1,365,936 per year, based on the higher rate of primary graft failure reported in the clinical literature.

2. Conventional Tissue Products

Conventional tissue includes a wide range of products including bone allograft, skin allograft, heart valves, and other products. FDA's survey of the clinical literature indicates that bone, skin and heart valve allograft each presents a different potential for product failure and thus different kinds of benefits from improved quality assurance in product manufacture. The discussion that follows considers three distinct areas of benefit.

a. *Bone allograft products.* An analysis of the incidence, nature, and treatment of infection in bone allograft (Ref. 7) by Lord et al. 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) of the infected allograft 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 grafts), in addition to factors such as the duration of the operation, loss of blood, injury to soft tissue, and skin sloughing during the operation. These risk factors highlight the critical need for tissue products that are both sterile and viable.

The importance of processing validation is implied by Hardin (Ref. 8) in a review of banked bone allograft processes. In describing methods for sterilization, Hardin lists ethylene oxide as one of the most commonly used chemicals, but indicates that its effectiveness may nonetheless be questionable, because of reports of graft failures in which residues of ethylene oxide have been blamed, 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 and an estimated 0.82 failure rate for infected bone allograft), and the assumption that all failures would be treatable through repeat surgery to replace the bone graft, the associated costs could be on the order of $33 million per year [$33,069,348 = 0.057 × 39,000 × ($13,538 + $1,338)]. This is based on a national estimate of 39,000 bone allograft per year[7] (Ref. 9), and an estimated $13,538 per hospitalization

[3] These AHCPR estimates are based on data from the Healthcare Cost and Utilization Project (HCUP–3) National Inpatient Sample. This is a Federal-State-industry partnership to assemble health care data, based on a nationwide inpatient sample of hospital discharge records for 1994, from 20 percent of U.S. community hospitals from 17 States. The HCUP–3 estimated hospital charges do not include physician payments.

[4] An estimated submitted charge of $76 per office visit for ophthalmology care is based on HFCA allowed payments for Medicare beneficiaries in the *Health Care Financing Review* 1997 Statistical Supplement Table 62, adjusted to estimate submitted charges.

[5] An estimated initial hospital visit charge of $214 and subsequent visit charge of $88, based on HFCA allowed payments for Medicare beneficiaries in the *Health Care Financing Review* 1997 Statistical Supplement Table 62, adjusted to estimate submitted charges.

[6] This estimate is based on the 1994 average total compensation of $36,834 adjusted by 2.9 percent annual increase between 1994 and 1997, per the *U.S. Statistical Abstract.* ($36,834 × 1,0293/2080) = $19.3

[7] *Detailed Diagnoses and Procedures, National Hospital Discharge Survey 1995*, Series 13: Data from the National Health Survey, No. 13, November 1997, table 4, p. 131.

for repeat surgery (AHCPR HCUP–3 NIS). Physician costs per hospitalization are estimated to be $1,338 including $135 for each of two specialty physician office visits: one prior to, and one following hospitalization[8] (Ref. 6); and $1,068 for surgeon services while hospitalized, based on HCFA-reported average submitted charges per person served for orthopedic surgery[9] (Ref. 6).

The reported average length of stay for bone surgery is approximately 5 days. The estimated cost of patient time lost assumes that repeat surgery would require at least 1 week of time from work, at an estimated value of $772, based on a 40-hour work week and average hourly compensation of $19.30 (see footnote 6). This yields a total estimated patient time cost of $1,716,156 [0.057 × 39,000 × $772]. The total annual cost of bone allograft failure due to contamination is therefore estimated to be nearly $35 million [$34,785,504 = $33,069,348 + $1,716,156].

If bone allograft failures result in amputation, the direct and indirect costs would be significantly higher. For example, the cost per hospitalization for lower extremity amputation is estimated to be $24,178, based on the AHCPR HCUP–3 data. Moreover, permanent disability following amputation imposes extremely high costs on the patient, and on society.

FDA is uncertain about the extent to which the estimated cost impact will be reduced through CGTP for two reasons. First, some tissue graft failures may result from the transplant procedures rather than the bone allograft manufacture. Second, some facilities may have already developed new bone processing methods that may greatly reduce infection risk. If as much as 75 to 80 percent of the estimated risk is actually attributable to other factors, or has already been addressed through better manufacturing procedures at many facilities, the net benefit from the proposed CGTP rule applied to the remainder of bone tissue processes and facilities would be approximately $8 million [$34,785,504 × 0.23] per year.

b. *Skin allograft products.* Skin allograft represent another type of tissue product that is critically dependent on quality controls to prevent the manufacture and distribution of contaminated or defective products. The clinical literature reports cases of cytomegalovirus (CMV) transmission through skin donor infection (Ref. 10), and HIV contamination from infected donor tissue and subsequent skin tissue handling (Ref. 11). 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 injury and are therefore susceptible to potentially life-threatening CMV infections. These include pneumonitis, retinitis, gastroenteritis, hepatitis, and neurological complications (Ref. 10). Contamination of skin allograft can significantly affect burn patient survival. Because the clinical literature does not provide summary estimates of the risk of contamination of skin allografts, the agency is unable to quantify overall risk. The agency welcomes comment on the rate and severity of skin tissue contamination.

c. *Heart valve allograft.* Heart valve allograft, another conventional tissue product, provide another compelling case for process validation and quality control. Valve tissue contaminants not effectively removed in tissue processing have resulted in serious infections that, at minimum, require valve replacement and that may also result in patient death.

Sources of contamination of a valve allograft include the donor, the environment during harvesting and processing, and the operating room during implantation. Microbial contamination of valve tissue 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. 12) common contaminants found before disinfection consist of gastrointestinal and skin flora, including coliforms, viridans group streptococci, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Bacillus* species. In general, bacterial contamination can be effectively removed through standard disinfection procedures used in most 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 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 the tissue disinfection regimen is not effective in eradicating fungal contamination.

Fungal endocarditis is a rare but potentially fatal complication of allograft 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 0.0085). In one reported case, the infected patient needed subsequent surgery to replace the valve and required 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 the patients who had acquired fungal endocarditis after valve allograft implantation died within 2 weeks of diagnosis.

In their study, Kuehnert et al. describe the process controls used by AATB-affiliated facilities, including the establishment, validation, and documentation of decontamination protocols. Because these regimens have not been found effective against fungal contamination, AATB-affiliated facilities routinely discard tissue with documented fungal contamination. However, according to Kuehnert et al., the supplier of over 85 percent of all heart valve allograft 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 resulted in the tissue being distributed for patient use.

The proposed rule would require that all facilities validate the effectiveness of each step in processing, and would require that contaminated tissue that cannot be effectively disinfected be discarded or otherwise removed from processing for distribution. Based on the rates of infection and mortality risk reported by Kuehnert et al., and a total of 61,000 heart valve allografts reported per year by the National Hospital Discharge Survey (Ref. 13), there may be an estimated 519 cases per year [0.0085 × 61,000] of heart valve contamination causing fungal endocarditis. These contaminated valves may further cause an estimated 207 deaths per year [0.0085 x 0.40 x 61,000]. Changes in processing based on the proposed CGTP requirements would help to avoid these deaths. Substantial health care cost

[8] An estimated cost of $135 per service based on average submitted charges per service for ''All Other Physician'' specialty groups is used to estimate specialist office visit charges. This cost per service is reported in the *Health Care Financing Review* 1997 Statistical Supplement Table 59.

[9] See *Health Care Financing Review* 1997 Statistical Supplement Table 59, Submitted Charges, for Orthopedic Surgery.

savings could also be achieved through improved processing controls. Based on an average cost of $63,096 per hospitalization for implantation of a heart valve allograft (Ref. 5), and estimated physician charges of $6,796 per case, including repeat surgery and patient care during the average 13-day hospital stay. If the CGTP requirements avoided 80 percent of these valve infections, this might result in health care cost savings of up to $29 million [0.8 x 519 x $63,096 + $6,796)].

3. Stem Cell Products

According to the National Center for Health Statistics National Hospital Discharge Survey, approximately 8,000 stem cell transplant procedures were performed in 1994. Based on the AHCPR HCUP–3 NIS data for 1994 (Ref. 5), the average length of hospital stay for bone marrow transplant procedures was 35 days, with an average cost per stay of $168,573.

Promising outcomes from use of peripheral blood stem cells (PBSC) and cord blood-derived stem cells (CBSC) in lieu of bone marrow have resulted in increased collection and use of these products in stem cell transplants. For example, recent studies have respectively reported use of PBSC (rather than bone marrow) in 54 percent (Ref. 14) and 62 percent (Ref. 15) of cases. However, studies of stem cell products indicate that products manufactured by this industry can become contaminated during collection and processing. Moreover, the therapy-induced immunosuppression of the oncology patients who receive these products places them at particular risk for serious infection and subsequent mortality. Manufacturing methods conforming to good tissue practice are necessary to prevent this threat to the safety and effectiveness of stem cell therapies. For example, earlier investigations of PBSC reported that the large quantity of blood that must be processed to obtain adequate numbers of stem 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. 16).

Another quality concern with PBSC involves the maintenance of sterile integrity of the apheresis catheter and component throughout the period of leukopheresis, cryopreservation, thawing, and transfusion (Espinosa et al., 1996). Webb et al. (Ref. 14) 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 the bacteremia-induced fever and other clinical sequelae are considered reversible, infections present more serious risks in stem cell recipients than for the general population. Survival rates for hematopoietic stem cell transplantation are significantly reduced for patients that become critically ill. In a study of survival rates among stem cell recipients admitted to an intensive care unit, Price et al. (Ref. 15) 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., to predict probability of death controlling for other risk factors such as patient intubation, type of transplant, source of stem cells, human leukocyte antigen compatibility, type of malignancy and patient age, also found infection to be a significant predictor of mortality.

An estimated 15 patients per year 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, and 8,000 stem cell transplants reported for 1994, and assuming that 58 percent of stem cell transplants (the average of the two reported rates of PBSC transplant cited above) involve PBSC. Costs of treating patients who become infected after receiving contaminated stem cell product are based on an average AHCPR-reported hospital charge[10] (Ref. 5) of $17,981 per 9-day patient stay for treatment of bacterial infection. Estimated health care costs also include physician costs of $918 assuming one initial hospital visit, and daily follow-up visits during the patient stay[11] (Ref. 6). Patient time loss during the hospitalization is valued at $1,387, based on estimated hourly compensation of $19.30 (see footnote 4) and a 9-day hospital stay. Thus, the total annual cost impact of patient infection following transplant of contaminated PBSC products is estimated to be $304,290 [15 × ($17,981 + $918 + $1,387)].

In addition to avoided health care costs, eliminating the risk of contaminated products could yield a potential of seven avoided stem cell patient deaths per year, due to infection. This number reflects the excess mortality risk reported for stem cell recipients with infection versus those without infection. It is based on the following: (8,000 transplant procedures per year) × (58 percent of procedures with PBSC) × (2.41 percent PBSC patients receiving contaminated product) × (13.7 percent patients receiving contaminated product develop infection) × (57 percent to 13 percent) excess rate of death for stem cell recipients given presence of infection.

As bacterial contamination has also been documented in a study of cord blood processing, the proposed CGTP requirements for staff training and process validation would support similar risk reduction efforts across CBSC facilities. For example, a study by Kogler et al. (Ref. 17) found that during the initial 6 months of an unrelated 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.

4. Reproductive Tissue Products

Most aspects of cellular and tissue product manufacturing in the reproductive tissue industry would become newly regulated under the proposed CGTP rule. The affected establishments within this industry include sperm banks and ART facilities. Reports of the sensitivity of product quality to variations in tissue collection, technician skill, processing methods, environmental conditions, and other factors (Ref. 22), indicate that the risk of communicable disease transmission would be reduced by improving the proposed overall product quality, and economic benefits would be seen through improved patient outcomes from facility compliance with the proposed CGTP requirements.

The tissue used in commercial sperm banks is washed, processed, and cryopreserved donor sperm used for therapeutic donor insemination (TDI). The sperm are obtained generally from paid donors who have been screened and tested for infectious disease and certain genetic disease risks.

The tissues used in ART facilities include fresh or cryopreserved oocytes, sperm, zygotes, and embryos. The handling of tissues include but are not limited to: Retrieval of oocytes from a

[10] Based on AHCPR HCUP–3 National Inpatient Survey for 1994 hospital charges by principal diagnosis, ''bacterial infection, unspecified site'' ($17,891), *http://www.ahcpr.gov/data/94dcchpr.htm*. 1998.

[11] Physician charges are based on estimates of physician submitted charges using data reported in the Health Care Financing Review Statistical Supplement, 1997, table 62. Initial inpatient visit charge is estimated to be $214, and daily follow-up visits in the hospital are estimated to be $88 per visit. Thus total physician charges for care during the 9-day hospital stay are estimated to be $918.

female, collection of sperm from a male, in vitro fertilization (IVF), cryopreservation of fertilized oocytes not transferred in the same treatment cycle, and thawing of frozen fertilized oocytes. The success of in vitro fertilization, measured as the number of deliveries per IVF cycle, has gradually increased over the past decade or so, from 11 percent in 1985 to 18 percent in 1994 (Ref. 18). More recently, the Centers for Disease Control and Prevention (CDC) have reported average live birth pregnancy rates for ART clinics to be as high as 19.6 percent per cycle in 1995 and 22.6 percent per cycle in 1996 (Refs. 19 and 20).

Despite the increasing effectiveness of infertility treatment through ART, problems can occur in tissue processing. Adverse outcomes owing to problems with product quality can result from contamination that produces infection (e.g., HIV transmission) in the infertility patient (Ref. 21). Problems with ART facility processing of sperm or oocytes can also lead to reduced rates of fertilization, and unsuccessful IVF attempts, which would ultimately increase the number of transfer attempts. Each additional transfer attempt increases the risk of communicable disease with each attempt.

Where quality problems in tissue processing result in reduced embryo quality and lower probability of pregnancy, the patient, on average, needs to undergo more cycles of IVF to achieve a pregnancy that produces a live birth. The estimated patient cost per cycle ranges from $8,000 to $10,000 (Refs. 24 to 26).

The number of Americans who would potentially benefit from improved reproductive tissue processing is substantial. According to the 1995 National Survey of Family Growth (NSFG), (Ref. 28) 15.4 percent of American women 15 to 44 years of age, approximately 9.3 million women, have reported receiving infertility services. Approximately 600,000 women report receiving ART's, defined in NSFG to include artificial insemination and IVF services. The number of ART procedures annually has been increasing in recent years. According to the CDC (Ref. 29) a total of over 64,000 cycles of ART were performed by U.S. facilities in 1996, compared to approximately 60,000 cycles in 1995. The proposed CGTP rule, therefore, has the potential to benefit thousands of infertile couples.

Processes that affect product quality. Recent clinical literature reports a number of factors in the manufacturing process that could affect tissue quality. These factors include technician skill, equipment accuracy and reliability, methods used in laboratory processing, and environmental controls affecting product quality. Following process validation and quality controls that would be required under the proposed rule is expected to substantially reduce or eliminate detrimental variations, and thereby improve product quality.

Sperm processing occurs in both commercial sperm banks and ART facilities. Commercial sperm banks generally screen, wash, and cryopreserve donor sperm. ART facilities typically include an andrology laboratory that performs semen analysis and conducts IVF. Variations in methods and technician skills at various stages of sperm processing have been associated with variations in quality. Poor sperm quality increases the probability that additional tissue transfer procedures will be necessary. For example, in a study conducted to establish quality controls in semen analysis, Yeung et al. found that the subjective thresholds for judging sperm motility (a key measure of sperm function for diagnosis and treatment) differed for each technician performing the analysis (Ref. 30). The establishment of values for threshold velocities, and standards for technician training were identified as methods to improve consistency in technician assessments.

A study by Mahmoud et al. (Ref. 31) compared 10 different methods for estimation of sperm concentration (another key indicator of sperm quality) and reported substantial differences in the accuracy of laboratory assessments, depending upon the type of pipette and the method used. They found that although a few devices and methods produced accurate, low-variability estimates, others had a tendency to overestimate or to underestimate sperm concentration. These findings strongly support the need for equipment calibration and laboratory method validation.

In addition to processing steps related to the sperm quantity and quality, sperm processing for IVF typically requires that sperm be purified, removing semen fluid, cellular debris, white blood cells, and other contaminants that may interfere with fertilization. Many sperm separation methods have been developed and are in use in ART programs, including basic sperm washing, swim-down and swim-up techniques, refrigeration/heparin techniques, separation with Sephadex and Ficoll columns, separation with glass wool and Percoll gradient centrifugation (Refs. 32 to 34). No single method has become the standard, although some approaches may be more effective than others in preserving functional integrity. For example, when King et al. (Ref. 35) compared the effect of different antibiotics used in sperm washing, they found that some agents produced severe adverse effects on sperm motility and actually decreased sperm fertilizing capacity. The importance of product quality in this step of processing offers another example of the value of process validation in ensuring sperm product viability and thus successful fertility treatment for patients.

Environmental controls present another area with a demonstrated need for quality control in reproductive tissue processing. Environmental contamination may come from many sources, including the air, water or laboratory supplies. A study of laboratory air quality in ART facilities by Cohen et al. (Ref. 36) found that over 300 volatile organic compounds were detectable in spite of the use of centralized high efficiency particulate air (HEPA) filtration, generic but centralized carbon and pre-filtration, and numerous ionization units placed at strategic points in the laboratory. Potential sources of contaminants included vehicle and industrial emissions in outside air, use of plastics and disposable plasticware in the laboratory, equipment (e.g., freon leakage from refrigeration units), cleaning agents and equipment lubricants, and air flows from activities in adjacent areas of the building.

A more detailed study of these factors by Cohen et al. was prompted in part by the sudden and significant declines in clinical pregnancy and implantation rates that occurred at two points in time at an ART facility. In those instances, the pregnancy rate had declined by about 50 percent and subsequent implantation rates also declined. Their investigation revealed that, in the first instance of decline, a fumigation with pesticides had taken place in areas of the building adjacent to the ART facility, without notification given to the ART facility. The second episode of sudden decline corresponded to the installation of a redesigned air filter in the facility. Further air sampling also revealed that chemical contaminants produced in another area of the building, which was used as an outpatient surgery center and was not part of the ART clinic, could be detected in the embryo laboratory when more sensitive monitoring equipment was used. Cohen et al. proposed various measures to counter these potential sources of chemical air contamination in both the laboratory and the embryo

incubators. Laboratories without adequate environmental monitoring and controls would not be able to detect such degradations in air quality.

An earlier study of mouse embryos by Francis et al. reported that some brands of nonpowdered surgical gloves appear to be embryotoxic (Ref. 37). Temperature fluctuations during cell culture, and to a lesser extent, the time between retrieval and transfer, may also affect tissue quality and thus increase the probability of additional transfer attempts (Ref. 39).

The lack of experience and training of laboratory personnel also could increase the need for additional transfer attempts due to poor tissue quality. One study found that new embryologists needed several months to gain the experience to consistently predict nuclear maturity from cumulus-coronal morphology. Moreover, even when a stable prediction rate was reached, it rarely exceeded 72 percent accuracy (Ref. 40). Yet consistent assessments of product quality and transfer of high quality embryos to the patient are critical to increasing the overall success of IVF treatment and to minimizing transfer attempts.

Although there has been some Federal and some private sector standard setting and oversight in the reproductive tissue industry, existing standards do not provide the level of quality management and process quality assurance that would be required under the proposed CGTP rule for all tissue establishments. A voluntary accreditation program jointly offered by the CAP and the ASRM has been available to ART laboratories since 1992 (Refs. 41 and 42), and the number of facilities seeking accreditation has been increasing in recent years. The problems with product processing cited in recent clinical literature, however, suggest that although there is increasing interest in quality assurance, there are still substantial gains that could be made in tissue facilities, by implementing the proposed CGTP rule.

In addition to the benefits that would accrue directly from implementation of this proposed rule, individuals may reap ancillary benefits that could arise indirectly from the rule. Although the proposed rule would provide a direct benefit from the decreased risk of communicable disease transmission, the public, particularly couples seeking assistance in beginning a pregnancy, could receive an indirect economic benefit. Such ancillary economic benefit, although not certain, would be seen as an increase in ART facility success rates and a decrease in health costs associated with a reduction in the number of IVF attempts per live birth.

FDA cannot predict the precise impact from implementation of the proposed CGTP rule. To obtain an estimate of benefits and to capture a level of uncertainty, this analysis considers three potential scenarios and presents the results a range of possible outcomes. In general, it is assumed that the rule will affect the facilities with the lowest success rates and that these facilities would improve to some minimal level of performance from the implementation of good practices. In one scenario, benefits are assumed to be limited to the worst-performing quarter of all facilities. These facilities would improve to the level of the facility just better than the bottom one-fourth. In another scenario, the half of all facilities with the lowest success rates would improve to where they would be as good as the median facility. In a third scenario, implementation of the rule would not change ART facility success rates.

The scenarios consider only the cycles of treatment for younger women (age less than 35) for whom patient age is not likely to be a confounding factor affecting oocyte quality. Of the 22,811 fresh nondonor cycles of treatment for these patients at the 300 ART facilities reporting data for 1996, the average success rate was 28.65 live births per 100 cycles, and the median live birth pregnancy rate was 26.3 percent per cycle.

Scenario 1 assumes that the facilities currently achieving the lowest success rates (i.e., the lowest quartile of success rates reported for ART establishments) are able to increase their average success rate to the rate corresponding to the 25th percentile rate. This would represent a first step and as technology and techniques continue to improve, so would success rates. In the 1996 report, the 25th percentile rate was 19.7 live births per 100 cycles. FDA finds that raising the bottom quartile of 75 facilities, to 19.7 live births per 100 cycles, would reduce the IVF attempts from a reported 4,756 to an estimated 3,591 treatment cycles. This improvement would decrease transfer attempts and yield an estimated savings of $10.5 million for patients and other payers, based on an estimated average cost of $9,000 per cycle, and an estimated 1,165 avoided cycles [4,756 − 3,591].

Scenario 2 assumes that facilities in the lower half of the industry distribution are able to bring their success rates up to the median rate of 26.3 live births per 100 cycles. The increased success rate is assumed to be achieved through improvement in staff training and skill, processing validation, and quality control throughout the facility in accordance with the proposed CGTP rule. Under this scenario, the affected 150 facilities would reduce the number of IVF attempts from a reported 10,414 cycles to an estimated 7,662 treatment cycles, to achieve the same number of successful treatments. This would yield an estimated cost savings of $24.8 million for patients and other payers. This is based on an estimated 2,752 avoided cycles of treatment [10,414 − 7,662] and assumed average cost of $9,000 per cycle of IVF treatment.

At the other end of the spectrum, Scenario 3 provides for the possibility that this proposed rule would have no effect on success rates at ART facilities or the number of IVF attempts per live birth. In such a case, there would be no additional economic benefit beyond the benefits previously discussed, including an anticipated decrease in communicable disease transmission.

Couples seeking infertility care incur an indirect cost of time lost (e.g., work time) while undergoing treatment. Using an average hourly wage of $19.30[12] and assuming 6 hours of time (e.g., 4 hours for the female and 2 hours for the male patient) per couple per cycle of IVF treatment, the estimated value of the lost time would be as follows. Under Scenario 1, the estimated 1,665 avoided treatment cycles would yield a time gain valued at $192,807 [1,665 × $19.30 × 6]. Under Scenario 2, the 2,752 potentially avoided treatment cycles would yield a time gain valued at $318,682 [2,752 × $19.30 × 6]. Under Scenario 3, there would be no avoided treatment cycles and, thus, no quantifiable benefits.

C. Summary of Potential Benefits Resulting From Avoided Quality Problems in Processing of Cellular and Tissue Based Products

This analysis of benefits of the proposed CGTP rule has considered its impact on major sectors of the tissue industry by focusing on product quality problems cited in the literature. This review suggests that industry standards are not applied uniformly resulting in uneven product quality.

Table 10 provides a summary of the particular products and problems identified in the agency's survey of literature. FDA estimated the potential benefits of avoiding quality problems based on reported risks and national

[12] Estimated hourly compensation of $19.30 is based on the 1994 average total compensation of $36,834, adjusted by 2.9 percent annual increase reported in the 1997 *U.S. Statistical Abstract*.

data-based estimates of the number of patients undergoing related procedures. Depending on the particular industry sector, the potential quantified benefits from reduced health care costs are estimated to range from approximately $61,000 per year, to approximately $33.5 million per year. The total estimated potential quantified benefits range from a total of $41.9 million to $68.0 million. The actual level of benefits that would be realized through wide application of CGTP is uncertain, however, as the agency's projections are sensitive to numerous assumptions that appear plausible, but remain to be tested.

TABLE 10.—SUMMARY OF POTENTIAL BENEFITS OF PROPOSED CURRENT GOOD TISSUE PRACTICE BASED ON TISSUE PROBLEMS CITED IN REVIEWED LITERATURE

Tissue Industry Sector	Tissue(s) Considered	Avoided Problems with Tissue	Avoided Treatment or Outcome	Potential Cost Savings/ Year
Eye Tissue	corneal graft	graft failure	repeat surgery; increased graft attempts	$61,000 to $1.4 million
Conventional Tissue	bone allograft	bone infection; graft failure	repeat surgery/amputation; increased graft attempts	$8 million
Conventional Tissue	heart valve allograft	fungal endocarditis	repeat surgery/patient death; increased transplant attempts	$29.6 million 176 excess deaths
Peripheral Blood and Cord Blood Stem Cells	stem cell transplant	infection in cancer patients	hospitalization/patient death	$304,000 7 excess deaths
Reproductive Tissue	sperm, oocytes, zygotes, embryos	IVF[1] failure	additional IVF treatment cycles	$0 to 24.8 million
Total Potential Cost Savings/Year				$41.9 to $68.0 million

[1] In vitro fertilization

Uncertainties affecting the true level of benefit include: The actual extent of current CGTP compliance in each of the affected industries, the lack of more complete information about the incidence and severity of problems from processing of tissue products, the net impact of those quality problems on patient outcomes, and the size of the affected patient population. Because of the limits of available data, the foregoing analysis has focused on a limited set of tissue products. It is not certain how well these data represent the most critical areas or actual scale of risks in the tissue industry. For some products, such as demineralized bone, the industry has achieved important advances in processing that have improved the safety and effectiveness of its products. Thus, the analysis of benefits based on problem reports from several years ago may overstate the potential for improvements in the current best industry practice. In other cases, the publication of the recent problem reports suggests that deficiencies still exist within current practices. These areas present important opportunities to avoid unnecessary patient risks and health care costs.

D. Small Entity Impacts

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a proposed rule may have a significant effect on a substantial number of small entities. Tissue and blood banks are classified in North American Industry Classification System (NAICS) 621991. In this industry category, any firm with annual revenues less than $5.0 million is considered small by the U.S. Small Business Administration. In every sector of the cell and tissue product industry, the majority of establishments are estimated to be classified as small entities. However, because of the high level of current compliance with industry standards, the increase in costs is expected to be limited primarily to facilities that do not comply with industry standards. To measure the impact of CGTP on small businesses, FDA calculated the ratio of industry compliance costs to industry revenues, assuming that all facilities incurred the same cost. The small entity impacts estimated below focus on the facilities that will be newly compliant under the proposed CGTP, and thus will experience the highest potential new costs. In addition, although current quality management practices at non-accredited or less-than-fully compliant facilities may vary, and not every facility will incur every new cost estimated in table 2, the analysis that follows considers a high-cost scenario where every estimated cost is incurred, in order to produce a conservative estimate of the potential impact on small entities. While some firms may have lower than average revenues, making them potentially more sensitive to cost increases, FDA does not know the distribution of firms by revenues. FDA welcomes comments on this issue.

Within the eye banking industry, experts estimate that virtually all facilities would be classified as small, and believe all are to be compliant with the industry EBAA standards. The average annual revenue per eye bank is estimated at $1.2 million (Ref. 44). If an eye bank were to incur every new cost estimated for facilities in that industry, the total cost impact, including total one-time costs and the yearly cost, would be $36,738, which represents an estimated 3 percent (0.03) of estimated annual revenues. Average annualized compliance costs per eye bank are estimated to be $10,717, or 0.89 percent of annual revenue per firm.

In the conventional tissue industry, an estimated 75 to 80 percent of the total of 110 facilities would be classified as small entities. Industry experts also estimate that 75 to 80 percent of those facilities currently comply with the AATB standards, which generally meet or exceed the requirements of the proposed CGTP rule. Based on the assumed levels of increased effort and costs shown in table 2, the remaining 23 percent of small facilities that do not comply with AATB standards would incur up to $62,662 in total new costs, including both the total one-time cost and the yearly cost, assuming that every potential area of new quality management effort would be needed at every one of these facilities. The average annual revenue per small conventional tissue bank is estimated at $1.2 million (Ref. 44). The estimated total new costs would represent approximately 5 percent of this annual revenue figure. The average annualized compliance cost for a small conventional tissue bank is estimated to be $10,310, representing 0.86 percent of firm revenues.

The agency anticipates that all stem cell facilities would be classified as small entities, and estimates that these establishments have annual revenue averaging $1.2 million (Ref. 44). Establishments that comply with the current FAHCT or AABB standards would incur some additional costs. If each of these facilities were to incur new costs for every provision identified in table 2, the total cost per facility, including total one-time and yearly costs, would be approximately $20,270. This figure represents approximately 2 percent of estimated annual revenues. Stem cell facilities that do not currently comply with AABB or FAHCT standards would incur greater costs, as shown in table 2. If each of these facilities were assumed to incur every new cost identified in the cost analysis, the total one-time cost plus annual cost would be approximately $79,337. This figure is equal to approximately 7 percent of estimated annual revenues. The average annualized compliance costs incurred by stem cell facilities would similarly vary depending on current facility practices and compliance with AABB or FAHCT standards. If a facility is currently compliant with these industry standards, the average annualized cost of compliance with the proposed rule is estimated to be about $7,407, representing 0.62 percent of the yearly revenue of these firms. However, if a facility is not currently compliant with the requirements of the current industry standards, a greater level of new effort would be required for quality assurance and quality management. The average annualized cost per facility is estimated to be $40,721, which would represent 3.39 percent of an average annual revenue of $1.2 million.

Consultants estimate that approximately two-thirds of all ART facilities (approximately 200) would be classified as small entities, and have average annual revenues of $2.5 million. Based on the project levels of compliance with various provisions of CGTP, as described in the cost analysis, if a facility were to incur every potential new cost, as shown in table 2, the total one-time plus annual cost to the facility would be $83,302. This total would represent approximately 3 percent of average annual revenues. The average annualized compliance cost per facility is estimated to be $11,342, representing approximately 0.45 percent of annual revenues.

According to recent estimates by a sperm banking industry expert, approximately 100,000 TDI units are produced each year from collected and processed sperm donations. An estimated 95 percent of that total production is handled by the largest 20 facilities. Nineteen of the largest 20 facilities are estimated to have average annual revenues of approximately $2 million, and only 1 of the 20 is estimated to have revenues greater than $5 million per year. The remaining 5 percent of industry production, or 5,000 TDI units, are processed by very small banks described by an industry expert as typically functioning within a physician office practice (e.g., that of an obstetrician (ob) or a gynecologist (gyn)). The sperm banking in these facilities is generally offered as an additional service to patients receiving fertility treatment, and is not the primary line of business of these establishments. The annual revenue for these individual physician practices is estimated to be $252,000 per year, based on the mean physician income of $215,000 after expenses and before taxes for the ob/gyn specialty category, reported in the 1992 American Medical Association (AMA) survey (Ref. 45), adjusted to 1998 assuming an average annual wage inflation of 2.7 percent, based on yearly rates reported by the Bureau of Labor Statistics. Thus the majority of sperm banks would be considered small entities.

If each of the small sperm banks were to incur every potential new cost of compliance with the proposed CGTP rule, as shown in table 2, the total one-time cost plus annual cost would equal $83,302, which would be approximately 4 percent of the $2 million in annual revenues for the ''larger'' small facilities. The average annualized cost to these banks is estimated to be $11,007, representing approximately 0.55 percent of annual revenues. Although these cost figures would account for a much larger percentage of individual physician practice income, the sperm banking provided by these establishments is considered to represent a small and generally nonessential part of their business. For the smallest banks, the estimated 5,000 TDI units supplied by the estimated 90 facilities translates to an average volume of 55 units per facility per year. With an estimated price of $95 to $145 per TDI unit (Ref. 46) and an estimated profit of 15 percent, the banks would realize a net income of $12.40 to $19.00 per unit, or average net income of $682 to $1,045 for 55 units. This income would represent only 0.3 percent (0.0027) to 0.4 percent (0.0041) of the estimated $252,000 in annual net income for the ob/gyn physician practice. Thus, it seems likely that physician practices that currently operate small-scale sperm banking may prefer to discontinue banking, and refer their patients to a commercial bank for this service.

In summary, the majority of facilities within each sector of the tissue industry are expected to qualify as small entities. The actual cost impact on each facility is uncertain because of the limited information available to describe the current practices and compliance with industry standards at each of these facilities and within each distinct industry sector. Based on the limited available data and expert opinions, the agency estimates impacts that would result in an average annualized cost per facility ranging from $ 7,000 to $11,000 for facilities that currently comply with an industry standard, to over $40,000 in average annualized costs for facilities that do not currently comply with most industry quality standards. These annualized costs represent 0.45 to 3.39 percent of the estimated total average annual revenues.

The agency is uncertain about the accuracy of these estimates, however, because of the lack of good data on revenues for these facilities. Because of the importance of this information in accurately assessing the impact on small entities, the agency requests that industry provide detailed comment on the percentage of facilities that qualify as small entities in the eye tissue, conventional tissue, stem cell, and reproductive tissue industries; the percentage of those facilities that fully comply with current industry standards; and the specific areas where industry anticipates substantial differences between current manufacturing practices and the quality assurance elements specified under the proposed rule. For those areas of identified difference, the agency further requests estimates of the resources and costs that will be required for facility compliance.

Although the proposed rule would impose some costs on small entities involved in the manufacture of cellular and tissue-based products, the agency believes that the proposed approach represents an effective means of protecting patient safety and public health in the manufacture of human cellular and tissue-based products. The less burdensome alternative to the proposed approach, i.e., continue with the use of trade organizational standards by industry, involve fewer requirements for small entities (the vast majority of facilities in this industry), but fail to provide fundamental aspects of product safety. Reliance on trade organization voluntary standards for good tissue practice, rather than establishing a regulatory requirement, would not ensure uniform or consistent

compliance and would preclude the agency's ability to effectively monitor tissue products to ensure public health and safety. While each trade organization varies in their standards or guidelines, regulatory requirements for good tissue practice would help ensure consistency among manufacturers. FDA finds that this proposed rulemaking would enhance both public health and public confidence in the safety and quality of cellular and tissue-based products, while imposing only a minimum burden on the affected industry sectors.

IX. References

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X. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 350193520). A description of these provisions is shown below 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.

FDA invites comments on: (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.

Title: Reporting and Recordkeeping Requirements in Current Good Tissue Practice.

Description: Under the authority of section 361 of the PHS Act, FDA is proposing new regulations to require manufacturers of human cellular and tissue-based products to follow CGTP, which would include information collection provisions such as the establishment and maintenance of SOP's, recordkeeping, reporting, and labeling of the products. The CGTP information collection provisions would provide: (1) additional measures for preventing the introduction, transmission, or spread of communicable diseases; (2) step-by-step consistency in the manufacturing of the product; (3) necessary information to FDA for the purpose of protecting public health and safety; (4) accountability in the manufacturing of cellular and tissue-based products; (5) information for meaningful FDA inspections; (6) information facilitating the tracking of a product back to its original source or to a recipient; (7) information to FDA of any adverse reaction; and (8) information that would aid in the investigation of any introduction, transmission, or spread of a communicable disease.

Table 11 lists provisions that would require reporting or disclosure of information to third parties, the Federal government, or the public. Section 1271.155(a) would require 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 of the proposed rule. When documentation on the determination of donor suitability is translated into English, § 1271.270(c) would require a statement of authenticity by the translator. Section 1271.290(c) would require a unique identifier be affixed to each cellular or tissue-based product to relate the product to the donor and all records pertaining to the product. Whenever an establishment initially distributes product to a consignee, § 1271.290(f) would require the establishment to inform the consignee, in writing, of the product tracking requirements and the methods the establishment uses to fulfill the requirements. Establishments described in proposed § 1271.10 would be required under proposed § 1271.350(a) and (b) to report to the agency any adverse reaction or any error or accident that may reasonably be expected to lead to a reportable adverse reaction as defined in proposed § 1271.3(ee). Section 1271.370(a)(2) and (a)(3) would require establishments to include specific information on the product label and package insert.

Table 12 lists recordkeeping provisions under the proposed rule, establishments would be required to prepare and maintain written SOP's for all significant steps performed in the manufacturing and tracking of human cellular and tissue-based products. As calculated in table 12, the preparation of the SOP's would result in a one-time impact on establishments rather than the year to year maintenance of the SOP's because, once composed, SOP's would only be reviewed annually and updated as necessary.

The SOP provisions proposed under part 1271 in the combined maintenance estimate include: (1) § 1271.160(b)(2) (receiving, investigation, evaluating, and documenting information received from other sources); (2) § 1271.160(f) (quality program); (3) § 1271.180 (all significant steps performed in the manufacture of human cellular and tissue-based products); (4) § 1271.190(c)(3) (facility cleaning and sanitization); (5) § 1271.195(a) (control and monitoring of environmental conditions); (6) § 1271.200(b) (cleaning, sanitizing, and maintenance of equipment); (7) § 1271.200(c) (calibration of equipment); (8) § 1271.210(a) (receipt and verification of supplies and reagents); (9) § 1271.210(b) (validation and/or verification of in-house reagents); (10) § 1271.220(b) (use and removal of processing material); (11) § 1271.220(d) (control of in-process product); (12) § 1271.225(a) (verification or validation of changes to a process); (13) § 1271.230(d) (maintenance and control of validated processes); (14) § 1271.250 (labeling of human cellular and tissue-based products); (15) § 1271.265(a) to (c) (receipt, acceptance or rejection, distribution, and destruction or other disposition of human cellular or tissue-based products); (16) § 1271.265(f) (suitable for return to inventory); (17) § 1271.270(b) (records management system); (18) § 1271.290(b) (method of product tracking); and, (19) § 1271.320(a) (review, evaluation, and documentation of all complaints).

Proposed part 1271 would require the following additional recordkeeping provisions listed under table 12. Section 1271.155(f) would require 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) would require documentation of corrective actions taken as a result of an audit of the quality program. Section 1271.160(b)(7) would require documentation of all product deviations in manufacturing cellular or tissue-based products. Section 1271.160(d)(3) would require documentation of the results of all audits and reaudits of the quality program. Section 1271.160(e) would require documentation of computer validation activities and results when computers are used as part of the quality program, as part of manufacturing, or for maintaining data or records. Section 1271.170(d) would require the maintenance of records of education, experience, training, and retraining of all personnel. Section 1271.190(c)(4) would require documentation of all significant facility cleaning and sanitation. Section 1271.195(c) would require documentation of environmental control and monitoring activities. Section 1271.200(e) would require documentation of all equipment maintenance, cleaning, sanitizing, calibration, and other activities. Section 1271.210(c) would require documentation of the receipt, verification, and use of each supply or reagent. Section 1271.220(b) and (d) would require documentation of the adequate removal of processing material and the verification activities for in-process product. Section 1271.225(b) would require documentation of all changes to established processes, including rationale and the date of implementation. Section 1271.230(a) would require documentation of validation activities when the results of a process cannot be fully verified by subsequent inspection and tests. Section 1271.230(b) would require documentation of the validation of any process-related claim. Section 1271.230(e) would require documentation of the review and evaluation of a process and revalidation of the process, if necessary, when any changes to or deviations from a validated process occur. Section 1271.260(b)(3) and (d) would require documentation of the storage temperature of human cellular and tissue-based products and any corrective action taken when acceptable storage conditions are not met. Section 1271.265(a) and (b) would require documentation of the receipt, acceptance or rejection, distribution, and destruction or other disposition of a human cellular or tissue-based product. Section 1271.270(a) and (c) would require documentation of each significant step in manufacturing required in subparts C and D of part 1271, the results and interpretation of all testing and screening for relevant communicable disease agents and diseases, and the determination of donor suitability.

Section 1271.180 would require the retention of obsolete procedures for 10 years. Section 1271.270(e) would require the retention of all records for a period of 10 years after their creation. Records pertaining to a particular human cellular or tissue-based product would be required to be retained at least 10 years after the date of implantation, transplantation, infusion, or transfer of the product. If the date of implantation, transplantation, infusion, or transfer is not known, then records would be required to be retained at least 10 years after the date of the product's distribution, disposition, or expiration, whichever is latest. This retention time is necessary because certain cellular and tissue-based products 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 a donor later determined to be at risk for communicable disease agents or diseases.

Section 1271.270(f) would require documentation of any contract, agreement, or other arrangement with another establishment under which any step in the manufacturing process is performed by the other establishment. Section 1271.290(e) would require documentation of the disposition of each of its human cellular or tissue-based product as part of its tracking method. Section 1271.290(f) would require an establishment to document that a consignee agreed to participate in its tracking method and will take all necessary steps to ensure compliance with the requirements of the regulation. Section 1271.320(b) would require an establishment to maintain a record of each complaint that it receives, including a review and evaluation. Section 1271.350(c) would require the documentation of adverse reaction reports, errors and accidents in manufacturing that may lead to product deviation reports, and the investigation of these reports.

Description of Respondents: Manufacturers of cellular and tissue-based products.

FDA estimates the burden of this collection of information as follows:

TABLE 11.—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)	1,065	1	1,065	3	3,195
1271.270(c)	1,065	1	1,065	1	1,065
1271.290(c)	791	250	198,215	0.08	15,857
1271.290(f)	1,065	1	1,065	1	1,065
1271.350(a)	1,065	6	6,390	0.5	3,195
1271.350(b)	1,065	2	2,130	0.5	1,065
1271.370(a)(2) and (a)(3)	633	207	131,005	0.25	32,751
Total					58,193

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 12.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
One-time Burden (Creation of SOP's [2])	1,065	9	9,585	16	153,360
One-time Burden (Review of existing SOP's for compliance)	1,065	19	20,235	5	101,175

TABLE 12.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
SOP Maintenance (See previous list of 19 SOP's)	1,065	19	20,235	1	20,235
1271.155(f)	1,065	1	1,065	0.25	266
1271.160(b)(3)	483	2	966	6	5,796
1271.160(b)(7)	597	15	8,955	0.5	4,478
1271.160(d)(3)	558	1	558	13	7,254
1271.160(e)	597	5	2,985	0.25	746
1271.170(d)	483	1	483	1	483
1271.180	483	1	483	120	57,960
1271.190(c)(4)	558	12	6,696	1	6,696
1271.195(c)	822	12	9,864	1	9,864
1271.200(e)	483	12	5,796	1	5,796
1271.210(c)	597	12	7,164	1	7,164
1271.220(b) and (d)	91	781	71,070	0.08	5,686
1271.225(b)	1,065	2	2,130	1	2,130
1271.230(a)	755	1	755	1	755
1271.230(b)	980	1	980	1	980
1271.230(e)	1,065	1	1,065	1	1,065
1271.260(b)(3)	597	356	212,532	0.08	17,003
1271.260(d)	747	12	8,964	0.25	2,241
1271.265(a)	597	360	214,920	0.08	17,194
1271.265(b)	822	407	334,554	0.08	26,764
1271.270(a) and (c)	597	360	214,920	0.1	21,492
1271.270(f)	755	2	1,510	0.25	378
1271.290(e)	641	306	196,146	0.3	58,844
1271.290(f)	1,065	57	60,705	0.35	21,247
1271.320(b)	830	5	4,150	1	4,150
1271.350(c)	726	6	4,356	0.5	2,178
Total					563,380

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Standard operating procedures.

Under this proposed rule, 19 SOP's would be required as previously described. FDA is assuming that approximately 1,065 manufacturers would have to create up to 9 SOP's for a total of 9,585 records, and the agency estimates that it would take 16 hours per record to create 9 new SOP's for a total of 153,360 hours as a one-time burden. The agency estimates that up to 19 SOP's would already exist as a result of complying with current applicable regulations or following industry organizational standards. Approximately 1,065 manufacturers would have to review these 19 SOP's for compliance with the regulations, which would expend approximately 5 hours per SOP as a one-time burden. Annual SOP maintenance of existing SOP's is estimated to involve 1 hour annually per SOP, totaling 19 hours annually per recordkeeper.

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 proposed regulation may have. In estimating the burden, FDA compared the proposed regulations with the current voluntary standards of a number of industry organizations, such as, AATB, EBAA, AABB, FAHCT, and CAP, and the guidelines provided by ASRM. In those cases where a voluntary industry standard appears to be equivalent to a proposed 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 proposed rule may already be required to comply with regulations for manufacturers of human drugs or biological products, e.g., parts 210, 211, 312, 314, and 606 (21 CFR parts 312, 314, and 606).

FDA has estimated the reporting (table 11) and recordkeeping (table 12) burdens based upon the agency's 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 products 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 sperm banks and ART facilities.

The agency has estimated that there are approximately 1,065 manufacturers of cellular and tissue-based products (approximately 110 manufacturers of conventional tissue, 114 manufacturers of eye tissue, 425 manufacturers of peripheral and cord blood stem cells, 350 manufacturers of reproductive tissue, and 66 manufacturers of cellular or tissue-based licensed biological products or devices). FDA obtained these estimates of manufacturers (including percentage of members and nonmembers) from the various trade organizations and the agency's registration systems for biological product and device manufacturers. The total number of respondents and recordkeepers, 1,065, in the tables is decreased for each provision by the number of establishments that follow, as usual and customary practice, the applicable established trade organizational standards comparable to the CGTP requirements, i.e., AATB, EBAA, FAHCT, AABB, or CAP. FDA based the estimated numbers for ''Number of Respondents'' and ''Number of Recordkeepers'' on information provided by the trade organizations.

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 Recordkeeper'' were calculated using comparable burdens under drug GMP regulations, part 211, and GMP for blood and blood components, 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.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by February 7, 2001 to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has concluded that the proposed rule raises Federalism implications because it could preempt some States' laws regarding donated human cells and tissues. FDA currently is seeking comments from elected State and local government officials under Executive Order 13132 on: (1) The need for the proposed good tissue practice rule to prevent communicable disease transmission through human cellular and tissue-based products; (2) alternatives that would limit the scope of such national requirements or otherwise preserve State prerogatives and authority; (3) the proposed good tissue practice provisions; and (4) any other issues raised by this proposed rule possibly affecting State laws and authorities.

XII. Request For Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on this proposal by May 8, 2001. Two copies of any 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Comments received in response to the proposed GTP rule could support a change that will affect language in previously published proposed tissue rules. In the event that any tissue rule becomes effective before either or both of the remaining tissue rules become effective, FDA intends to make conforming amendments to those final rules at the same time the remaining tissue rules become effective.

List of Subjects in 21 CFR Part 1271

Human cellular and tissue-based products, Communicable diseases, HIV/AIDS, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act, and under the authority delegated to the commissioner of Food and Drugs, it is proposed to amend 21 CFR Chapter I as follows:

Part 1271 as proposed in the **Federal Register** of May 14, 1998 (63 FR 26744) and September 30, 1999 (64 FR 52696) is amended as follows:

PART 1271—HUMAN CELLULAR AND TISSUE-BASED PRODUCTS

1. The authority citation for 21 CFR part 1271 is revised to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

2. Section 1271.3 is amended by adding paragraphs (ff) through (tt) to read as follows:

§ 1271.3 Definitions.

* * * * *

(ff) *Available for distribution* means that the human cellular or tissue-based product has been determined to meet all release specifications and to be suitable for distribution.

(gg) *Adverse reaction* means a noxious and unintended response to any human cellular or tissue-based product 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).

(hh) *Processing material* means 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 human cellular or tissue-based product when it is made available for distribution.

(ii) *Complaint* means any written, oral, or electronic communication that alleges:

(1) That a human cellular or tissue-based product has transmitted or may have transmitted a communicable disease to the recipient of the product;

(2) That the function or integrity of a human cellular or tissue-based product may have been impaired; or

(3) Any other problem with a human cellular or tissue-based product that could result from the failure to comply with current good tissue practice.

(jj) *Distribution* means any conveyance or shipment of human cellular or tissue-based products (including importation and exportation), whether or not such conveyance or shipment is entirely intrastate and whether or not possession of the product is taken.

(kk) *Product deviation* means an event that represents a deviation from current good tissue practice, 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 a human cellular or tissue-based product to a recipient, or may lead to product contamination, or may adversely affect the function or integrity of the product.

(ll) *Establish and maintain* means define, document (in writing or electronically), and implement, then follow, review, and as needed, revise on an ongoing basis.

(mm) *Processing* means any activity other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution performed on a human cellular or tissue-based product, including but not limited to preparation, sterilization, steps to inactivate and remove adventitious agents, preservation for storage, and removal from storage.

(nn) *Quality audit* means 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.

(oo) *Quality program* means an organization's comprehensive system for manufacturing and tracking human cellular and tissue-based products. This program includes preventing, detecting, and correcting deficiencies that may lead to circumstances that increase the risk of introduction, transmission, or spread of communicable disease.

(pp) *Recovery* means the process of obtaining from a donor cells or tissues that are intended for use in human

implantation, transplantation, infusion, or transfer.

(qq) *Storage* means holding human cellular or tissue-based products for future processing and/or distribution.

(rr) *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 product meeting its predetermined specifications.

(ss) *Verification* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

(tt) *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.

3. Subpart D, consisting of §§ 1271.150 through 1271.320, is added to part 1271 to read as follows:

Subpart D—Current Good Tissue Practice

Sec.
1271.150 Current good tissue practice: general.
1271.155 Exemptions and alternatives.
1271.160 Establishment and maintenance of a quality program.
1271.170 Organization and personnel.
1271.180 Procedures.
1271.190 Facilities.
1271.195 Environmental control and monitoring.
1271.200 Equipment.
1271.210 Supplies and reagents.
1271.220 Process controls.
1271.225 Process changes.
1271.230 Process validation.
1271.250 Labeling controls.
1271.260 Storage.
1271.265 Receipt and distribution.
1271.270 Records.
1271.290 Tracking.
1271.320 Complaint file.

Subpart D—Current Good Tissue Practice

§ 1271.150 Current good tissue practice: general.

(a) *General*. Current good tissue practice (CGTP) requirements are set forth in this subpart and in subpart C of this part. CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of human cellular and tissue-based products, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The CGTP requirements are intended to prevent the introduction, transmission, and spread of communicable disease through the use of human cellular and tissue-based products by helping to ensure that the products do not contain communicable disease agents; that the products do not become contaminated during manufacturing; and that the function and integrity of the products are not impaired through improper manufacturing. The CGTP provisions specifically governing determinations of donor suitability, including donor screening and testing, are set out separately in subpart C of this part.

(b) *Compliance with applicable requirements*. (1) If an establishment engages in only some operations subject to the regulations in this subpart and subpart C of this part, and not others, that establishment need only comply with those requirements applicable to the operations in which it engages. However, 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 requirements in this subpart and subpart C of this part.

(2) The establishment that determines that a product meets release criteria and makes the product available for distribution, whether or not that establishment is the actual distributor, is responsible for ensuring that the product has been manufactured in compliance with the requirements of subparts C and D of this part and any other applicable requirements.

(c) *Compliance with parts 210, 211, and 820 of this chapter*. With respect to human cellular or tissue-based products regulated as biological drugs or devices under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic 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, shall be considered to supplement, not supersede, each other unless the regulations explicitly provide otherwise. 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.

(d) *Where appropriate*. When a requirement is qualified by ''where appropriate,'' it is deemed to be ''appropriate'' unless the establishment can document justification otherwise. A requirement is ''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.

§ 1271.155 Exemptions and alternatives.

(a) *General*. An establishment may request an exemption or alternative from any requirement in subpart C or D of this part regarding a human cellular or tissue-based product.

(b) *Request for exemption or alternative*. A request under this section shall be submitted to the Director, Center for Biologics Evaluation and Research (the Director). The request shall be accompanied by supporting documentation, including all relevant valid scientific data. A request for an exemption shall contain information justifying the exemption. A request for an alternative shall contain a description of an alternative that satisfies the purpose of the requirement.

(c) *Criteria for granting 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 preventing the introduction, transmission, and spread of communicable disease and that:

(1) The information submitted justifies an exemption; or

(2) The proposed alternative satisfies the purpose of the requirement.

(d) *Form of request*. A request for an exemption or alternative shall ordinarily be made in writing or electronically. However, in limited circumstances such a request may be made orally, and an exemption or alternative may be granted orally by the Director. An oral request and approval shall be followed by an immediate written request and written acknowledgment of approval.

(e) *Operation under exemption or alternative*. An establishment shall not begin operating under the terms of a requested exemption or alternative until the exemption or alternative has been granted in writing. An establishment may apply for an extension of an exemption or alternative beyond its expiration date, if any.

(f) *Documentation*. An establishment operating under the terms of an exemption or alternative shall maintain documentation of:

(1) FDA's granting of the exemption or alternative, and

(2) The date on which it began operating under the terms of the exemption or alternative.

§ 1271.160 Establishment and maintenance of a quality program.

(a) *General*. An establishment that performs any step in the manufacture of

human cellular and tissue-based products shall establish and maintain a quality program that is appropriate for the specific human cellular and tissue-based products manufactured and the manufacturing steps performed and that meets the requirements of this subpart.

(b) *Functions*. Functions of the quality program shall include, but not be limited to:

(1) Ensuring that appropriate procedures are established and maintained, and ensuring compliance with the requirements of § 1271.180 with respect to procedures, including review, approval, revision, and archiving;

(2) Ensuring that procedures exist for receiving, investigating, evaluating, and documenting information received from other sources and for sharing with consignees and other establishments that are known to have recovered cells or tissue from the same donor any information pertaining to the integrity and function of a human cellular or tissue-based product, possible contamination of the product, or the potential transmission of communicable disease by the product. In the case of information received after the product is made available for distribution or shipped to the consignee, procedures shall include provisions for evaluating the effect this information has on the product and for the notification of all entities to whom affected product was distributed, the quarantine and recall of the product, and/or reporting to FDA, as necessary.

(3) Ensuring that appropriate corrective actions, including reaudits of deficiencies, are taken and documented, as necessary. Corrective actions shall be verified to ensure that such actions are effective and do not adversely affect the finished product. Where appropriate, corrective actions shall include both short-term action to address the immediate problem and long-term action to prevent the problem's recurrence. Documentation of corrective actions shall include where appropriate:

(i) Identification of the human cellular or tissue-based product 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;

(5) Establishing and maintaining appropriate monitoring systems as necessary to comply with the requirements of this subpart (e.g., environmental monitoring);

(6) Establishing and maintaining a system for the maintenance of records in compliance with § 1271.270;

(7) Investigating and documenting all product deviations and making reports if required under § 1271.350(b) or other applicable regulations. Each investigation shall include a review and evaluation of the product deviation, the efforts made to determine the cause, and the implementation of corrective action(s) designed to address the product deviation and prevent recurrence. Each establishment shall also perform a periodic review and analysis of all product deviations, at least once each year, for the purpose of identifying trends and adopting appropriate preventive measures. This analysis shall be available for review upon inspection and for submission to FDA upon request; and

(8) Conducting evaluations, investigations, audits, and other actions necessary to ensure compliance with the requirements of this subpart.

(c) *Authority over program*. One or more designated persons shall have authority over and responsibility for ensuring that the quality program is effectively established and effectively maintained. This person shall report to management on the performance of the quality program on no less than an annual basis. If this person also performs other tasks in the establishment, he or she shall not have final oversight over his or her own work.

(d) *Audits*. (1) A comprehensive quality audit, as defined in § 1271.3(nn), shall be performed no less than once in a 12-month period. Special audits shall be performed as necessary. All audits shall be conducted in accordance with procedures to assure that the quality program is operating effectively and to identify trends or recurring problems.

(2) Quality audits shall be conducted by individuals with sufficient knowledge, training, and experience to identify problems in the specific processes under review, but who do not have direct responsibility for the processes being audited.

(3) A documented report of the results of the audits and reaudits, where taken, shall be retained. Such reports shall be reviewed by management having responsibility for the matters audited, and this management review shall be documented.

(e) *Computers*. If computers or automated data processing systems are used as part of the quality program, as part of manufacture or tracking, or for maintaining data or records related to the manufacture or tracking of human cellular or tissue-based products, the establishment shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

(f) *Procedures*. Procedures shall be established and maintained for a quality program, including quality audits.

§ 1271.170 Organization and personnel.

(a) *General*. Each establishment shall maintain an adequate organizational structure and sufficient personnel to ensure that the requirements of this part are met.

(b) *Competent performance of functions*. Each establishment shall have sufficient personnel with the necessary education and experience to assure competent performance of their assigned functions. Personnel shall perform only those activities for which they are qualified.

(c) *Training*. All personnel shall be trained, and retrained as necessary, to perform their assigned responsibilities adequately. Personnel shall be made aware of possible consequences of improper performance of their duties; e.g., the risk of transmission of communicable disease agents and diseases, and the hazards associated with those disease agents and diseases, and the risk of adversely affecting function and integrity of human cellular and tissue-based products.

(d) *Records*. A record of the education, experience, training, and retraining shall be maintained for all personnel.

§ 1271.180 Procedures.

Each establishment shall establish and maintain procedures for all significant steps that it performs in the manufacture of human cellular and tissue-based products. These procedures shall be designed to prevent circumstances that increase the risk of the introduction, transmission, and spread of communicable disease through the use of human cellular and tissue-based products by ensuring that the products do not contain relevant communicable disease agents; that the products do not become contaminated during manufacturing; and that the function and integrity of the products are not impaired through improper manufacturing. Procedures shall be designed to ensure compliance with the requirements of this part. Prior to implementation, all procedures shall be reviewed and approved by a responsible person. At least once in a 12-month period, all procedures shall be reviewed and, if necessary, revised, and the

review shall be documented. Procedures shall be readily available to the personnel in the area where the operations to which they relate are performed, unless this is impractical. Any deviation from a procedure shall be authorized in advance by a responsible person, recorded, and justified. An establishment may adopt current standard procedures, such as those in a technical manual prepared by another organization, provided the procedures are consistent with and at least as stringent as the requirements of this part and appropriate for the operations conducted at the establishment. Obsolete procedures shall be archived for at least 10 years.

§ 1271.190 Facilities.

(a) *General.* Any facility used in the manufacture of human cellular or tissue-based products shall be of suitable size, construction, and location to facilitate cleaning, relevant maintenance, and proper operations. The facility shall be maintained in a good state of repair. Adequate lighting, ventilation, plumbing, drainage, and washing and toilet facilities shall be provided.

(b) *Operations.* A facility used in the manufacture of human cellular or tissue-based products shall be divided into separate or defined areas of adequate size for each operation that takes place in the facility, or other control systems shall be established and maintained to prevent improper labeling, mix-ups, contamination, cross-contamination, and accidental exposure of human cellular and tissue-based products to communicable disease agents.

(c) *Facility cleaning and sanitation.* (1) Any facility used in the manufacture of human cellular and tissue-based products shall be maintained in a clean, sanitary, and orderly manner.

(2) Sewage, trash, and other refuse shall be disposed of in a timely, safe, and sanitary manner.

(3) Procedures for facility cleaning and sanitation shall be established and maintained. These procedures shall assign responsibility for sanitation and shall describe in sufficient detail the cleaning methods to be used and the schedule for cleaning the facility.

(4) All significant cleaning and sanitation activities shall be documented, and records shall be maintained.

§ 1271.195 Environmental control and monitoring.

(a) *General.* Where environmental conditions could reasonably be expected to have an adverse effect on the function or integrity of human cellular and tissue-based products, or to cause contamination or cross-contamination of products or equipment or accidental exposure of products to communicable disease agents, procedures shall be established and maintained to adequately control and monitor environmental conditions and to provide proper conditions for operations. Where appropriate, these procedures shall provide for the following control and monitoring 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;

(4) Maintenance of equipment used to control conditions necessary for aseptic processing operations; and

(5) Environmental monitoring for organisms.

(b) *Inspections.* Each environmental control system shall be inspected periodically to verify that the system, including necessary equipment, is adequate and functioning properly. Appropriate corrective action shall be taken as necessary.

(c) *Records.* Environmental control and monitoring activities shall be documented, and records shall be maintained.

§ 1271.200 Equipment.

(a) *General.* Equipment used in the manufacture of human cellular and tissue-based products shall be of appropriate design for its use, shall be suitably located and installed to facilitate operations, including cleaning and maintenance, and shall not have any adverse effect on the products. Any automated, mechanical, electronic, computer, or other equipment used for inspection, measuring, and testing shall be capable of producing valid results.

(b) *Procedures and schedules.* Procedures shall be established and maintained for cleaning, sanitizing, and maintaining equipment to prevent malfunctions, contamination or cross-contamination, accidental exposure of human cellular and tissue-based products to communicable disease agents, and other events that could reasonably be expected to have an adverse effect on product function or integrity. Cleaning, sanitizing, and maintenance of equipment shall be performed according to established schedules.

(c) *Calibration of equipment.* All automated, mechanical, electronic, computer, or other equipment used for inspection, measuring, and testing shall be routinely calibrated according to established procedures and schedules. Calibration procedures shall include specific directions and, where applicable, shall include limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for corrective action to reestablish the limits and to evaluate whether there were any adverse effects on any human cellular or tissue-based product.

(d) *Inspections.* Equipment shall be routinely inspected for cleanliness, sanitation, and calibration, and to assure adherence to applicable equipment maintenance schedules.

(e) *Records.* All maintenance, cleaning, sanitizing, calibration, and other activities performed in accordance with this section shall be documented and maintained. Records of recent maintenance, cleaning, sanitizing, calibration, and other activities shall be available at each piece of equipment. Records of the use of each piece of equipment, which shall include the identification of each human cellular or tissue-based product manufactured with that equipment, shall be maintained.

§ 1271.210 Supplies and reagents.

(a) *Receipt and verification.* Procedures shall be established and maintained for receiving supplies and reagents used in the manufacture of human cellular and tissue-based products. Supplies and reagents shall be verified to meet specifications designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable disease through product contamination or the impairment of product function or integrity, and shall not be used until such verification is completed. 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 human cellular and tissue-based products shall be of appropriate grade for the intended use and shall be sterile, if appropriate. Procedures for production of in-house reagents shall be validated and/or verified.

(c) *Records.* The following records pertaining to supplies and reagents shall be maintained:

(1) Records of the receipt of each supply or reagent, including the type, 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 use of each supply or reagent, which shall include the identification of each human cellular or tissue-based product manufactured with the supply or reagent.

§ 1271.220 Process controls.

(a) *General*. Each establishment engaged in the processing of human cellular or tissue-based products shall develop, conduct, control, and monitor its manufacturing processes to ensure that each human cellular or tissue-based product conforms to specifications, is not contaminated, maintains its function and integrity, and is manufactured so as to prevent transmission of communicable disease by the product.

(b) *Processing material*. Where a processing material could reasonably be expected to have an adverse effect on a human cellular or tissue-based product's function or integrity, the establishment shall establish and maintain procedures for the use and removal of such processing material to ensure that it is removed or limited to an amount that does not adversely affect the product's function or integrity. The removal or reduction of such processing material shall be documented.

(c) *Pooling*. Human cells or tissue from two or more donors shall not be pooled (placed in physical contact or mixed in a single receptacle) during manufacturing.

(d) *In-process monitoring*. Procedures shall be established and maintained, where appropriate, to ensure that specified requirements of in-process product are met. Such procedures shall ensure that in-process product 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 products shall be representative of the material to be evaluated.

§ 1271.225 Process changes.

(a) *Procedures*. Procedures shall be established and maintained for making changes to a process. Any such change shall be verified or validated, to ensure that the change does not create an adverse impact elsewhere in the operation, and shall be approved before implementation by a responsible person with appropriate knowledge and background.

(b) *Change records*. All changes to established processes shall be documented, including the rationale for the change and the date of implementation. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), approval date, and when the change becomes effective. Approved changes shall be communicated to the appropriate personnel in a timely manner.

§ 1271.230 Process validation.

(a) *General*. 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. The validation activities and results, including the date and signature of the individual(s) approving the validation, shall be documented.

(b) *Claims*. Any process-related claim in labeling or promotional materials for a human cellular or tissue-based product, e.g., a claim for sterility or viral inactivation, shall be based on a validated process. Validation shall be documented, and the documentation shall be maintained at the establishment and made available for review on inspection.

(c) *Dura mater*. Dura mater shall be processed using a validated procedure that reduces transmissible spongiform encephalopathy, while preserving the clinical utility of the product.

(d) *Procedures*. Procedures shall be established and maintained for monitoring and control of validated processes to ensure that the specified requirements continue to be met.

(e) *Changes and deviations*. When changes to or deviations from a validated process occur, the establishment shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

§ 1271.250 Labeling controls.

Procedures shall be established and maintained to control the labeling of human cellular and tissue-based products. These procedures shall be designed to ensure proper product identification and to prevent mix-ups. Procedures shall include verification of label accuracy, legibility, and integrity. Procedures shall ensure that each product is labeled in accordance with all applicable labeling requirements, including those in §§ 1271.55, 1271.65, 1271.75, 1271.90, 1271.290, and 1271.370, and that each product made available for distribution is accompanied by documentation of the donor suitability determination as required under § 1271.55.

§ 1271.260 Storage.

(a) *Control of storage areas*. Each establishment shall control its storage areas and stock rooms to prevent mix-ups, commingling, deterioration, contamination, and cross-contamination, of human cellular and tissue-based products and supplies, and any other condition that may adversely affect product function or integrity, and to prevent improper release for distribution.

(b) *Temperature*. (1) Each establishment shall store human cellular and tissue-based products at an appropriate temperature and for no longer than the maximum storage period for the product.

(2) Acceptable temperature limits for storage of human cellular and tissue-based products at each step of the manufacturing process shall be established to ensure product function and integrity, to prevent product deterioration, and to inhibit the growth of infectious agents.

(3) Storage temperatures for human cellular and tissue-based products shall be maintained and recorded. Recorded temperatures shall be reviewed periodically to assure that temperatures have not exceeded acceptable limits.

(c) *Expiration date*. Where appropriate, an expiration date shall be assigned to each human cellular or tissue-based product based on the following factors:

(1) Product type;

(2) Processing procedures, including the method of preservation;

(3) Storage conditions; and

(4) Packaging.

(d) *Corrective action*. Corrective action shall be taken and documented whenever proper storage conditions are not met.

§ 1271.265 Receipt and distribution.

(a) *General*. Procedures shall be established and maintained for the following activities: receipt, acceptance or rejection, distribution, and destruction or other disposition of human cellular or tissue-based products, and these activities shall be documented. Documentation shall include:

(1) Identification of the human cellular or tissue-based product;

(2) Activities performed and the results of such activities;

(3) Date(s) of activity;

(4) Quantity of human cellular or tissue-based product subject to the activity; and

(5) Disposition of the human cellular or tissue-based product (e.g., identity of consignee).

(b) *Receiving activities*. Procedures shall be established and maintained for

receiving and accepting or rejecting human cellular or tissue-based products for processing, distribution, or any other step in the manufacturing process. The status of each incoming human cellular or tissue-based product (e.g., with respect to quarantine, donor screening and testing, and processing) shall be determined and identified promptly after receipt, and each product shall be handled in a manner appropriate to its status. Each incoming human cellular or tissue-based product shall be inspected according to established procedures for damage, contamination, deterioration, or other indications that the integrity of the product has been impaired. Acceptance or rejection of incoming products shall be documented.

(c) *Availability for distribution.* Procedures shall be established and maintained for making human cellular and tissue-based products available for distribution. These procedures, which shall include release criteria, shall be designed to prevent the release of products that are in quarantine, are contaminated, have deteriorated, or otherwise have been manufactured in violation of current good tissue practice and, except as provided under §§ 1271.65 and 1271.90, products from donors who have been determined to be unsuitable or for whom a donor-suitability determination has not been completed. Prior to making a human cellular or tissue-based product available for distribution, the establishment shall verify and document that the release criteria have been met and shall review all records pertaining to the product. The determination that a human cellular or tissue-based product is available for distribution shall be documented and dated by a responsible person.

(d) *Packaging.* Packaging and shipping containers shall be designed, validated, and constructed to ensure product function and integrity and protect the product from damage, deterioration, contamination, or other adverse effects during customary conditions of processing, storage, handling, and distribution.

(e) *Shipping conditions.* Appropriate shipping conditions shall be defined for each type of human cellular or tissue-based product to be maintained during transit.

(f) *Return to inventory.* Procedures shall be established and maintained to determine if a product that is returned to an establishment is suitable to be returned to inventory.

§ 1271.270 Records.

(a) *General.* Records shall be maintained concurrently with the performance of each significant 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 record is subject to the requirements of this section. All records shall be accurate, indelible, and legible. The records shall identify the person performing the work, the dates of the various entries, and shall be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular human cellular or tissue-based product involved. Record security systems shall be adequate to ensure the confidentiality of donors and recipients of human cellular and tissue-based products.

(b) *Records management system.* A records management system shall be established and maintained. Under this system, records pertaining to a particular human cellular or tissue-based product manufactured shall be maintained in such a way as to facilitate review of the product's history prior to making it available for distribution and, if necessary, subsequent to the product's release as part of a follow-up evaluation or investigation. Records pertinent to the manufacture of each type of human cellular or tissue-based product (e.g., procedures, specifications, labeling and packaging procedures, equipment logs) shall also be maintained and organized under the records management system. If records are maintained in more than one location, then the records management system shall be designed to ensure prompt identification, location, and retrieval of all records.

(c) *Other recordkeeping requirements.* Procedures shall be established and maintained to ensure compliance with the recordkeeping requirements in § 1271.55. Documentation of results and interpretation of all testing for relevant communicable disease agents in compliance with §§ 1271.80 and 1271.85 shall be maintained, as well as the name and address of the testing laboratory or laboratories. Documentation of the results and interpretation of all donor screening for relevant communicable disease in compliance with § 1271.75 shall be maintained in accordance with § 1271.270. Documentation of the donor-suitability determination, including the name of the responsible person who made the determination and the date of the determination, shall also be maintained. Information on the identity and relevant medical records of the donor, as defined in § 1271.3(v), shall be in English or, if in another language, shall be translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

(d) *Methods of retention.* Records required under this subpart may be maintained electronically, as original paper records, or as true copies such as photocopies, microfiche, or microfilm, in which case suitable reader and photocopying equipment shall be readily available. Records stored in automated data processing systems shall be backed up. Electronic records and electronic signatures are subject to the requirements in part 11 of this chapter.

(e) *Length of retention.* All records shall be retained 10 years after their creation. However, records pertaining to a particular human cellular or tissue-based product shall be retained at least 10 years after the date of implantation, transplantation, infusion, or transfer of the product, or if the date of implantation, transplantation, infusion , or transfer is not known, then records shall be retained at least 10 years after the date of the product's distribution, disposition, or expiration, whichever is latest. Records for archived specimens of dura mater shall be retained 10 years after the appropriate disposition of the specimens. The establishment shall make provisions for all records to be maintained for the required period in the event that the establishment ceases operation.

(f) *Contracts and agreements.* Each establishment shall maintain records of any contract, agreement, or other arrangement with another establishment under which any step in the manufacturing process is performed by the other establishment. These records shall include the name and address of the other establishment and the responsibilities of each party to the contract, agreement, or other arrangement.

§ 1271.290 Tracking.

(a) *General.* Each establishment that performs any step in the manufacture of a human cellular or tissue-based product shall track each such product in accordance with this section.

(b) *Method of product tracking.* (1) Each establishment shall establish and maintain a method of product tracking that enables the tracking of all human cellular and tissue-based products from:

(i) The donor to the recipient or final disposition; and

(ii) The recipient or final disposition to the donor.

(2) Alternatively, an establishment that performs some but not all of the steps in the manufacture of a human cellular or tissue-based product may

participate in a method of product tracking that has been established and is maintained by another establishment responsible for other steps in the manufacture of the same product, provided that the tracking method complies with all the requirements of this section.

(c) *Distinct identification code.* As part of its tracking method, an establishment shall ensure that each human cellular and tissue-based product that it manufactures is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the product to the donor and to all records pertaining to the product. Except in the case of autologous or directed donations, such a code must be created specifically for tracking and may not include an individual's name, social security or medical record number. An establishment may adopt a distinct identification code assigned by another establishment engaged in the manufacturing process, or may assign a new code. An establishment that assigns a new code to a product shall establish and maintain procedures for relating the new code to the old code.

(d) *Product information.* As part of its tracking method, an establishment shall ensure that the identifier and type of each human cellular or tissue-based product that is implanted, transplanted, infused, or transferred into a recipient is recorded in the recipient's medical records, or in other pertinent records, to enable tracking from the recipient to the donor.

(e) *Recipient information.* As part of its tracking method, an establishment shall document, and maintain records of, the disposition of each of its human cellular or tissue-based products, to enable tracking from the donor to the recipient or final disposition. The information to be maintained shall permit the prompt identification of the recipient of the product, if any.

(f) *Consignees.* At or before the time of distribution of a human cellular or tissue-based product to a consignee, an establishment shall inform the consignee in writing of the requirements in this section and of the tracking method that the establishment has established and is maintaining to comply with these requirements. Upon initial distribution of product to the consignee, the establishment shall document that the consignee agreed to participate in its tracking method and to take all necessary steps to ensure compliance with the requirements of this section.

(g) *Requirements specific to dura mater donors.* Appropriate specimens from each donor of dura mater shall be archived, under appropriate storage conditions, and for the appropriate duration, to enable testing of the archived material for evidence of transmissible sponiform encephalopathy, and appropriate disposition of any affected dura mater tissue, if necessary.

§ 1271.320 Complaint file.

(a) *Procedures.* Each establishment shall establish and maintain procedures for the prompt review, evaluation, and documentation of all complaints, as defined in § 1271.3(ii), and the investigation of complaints as appropriate.

(b) *Complaint file.* Each establishment shall maintain a record of each complaint that it receives in a file designated for complaints. The complaint file shall contain sufficient information about each complaint for proper review and evaluation of the complaint, including the identifier of the human cellular or tissue-based product that is the subject of the complaint. The complaint file shall be made available for review and copying upon request from an authorized employee of the Food and Drug Administration.

(c) *Review and evaluation of complaints.* Each complaint shall be reviewed and evaluated to determine if the complaint is related to a product deviation of a human cellular or tissue-based product or to an adverse reaction, and to determine if a report under § 1271.350 or another applicable regulation is required. Each complaint that represents an event required to be reported to FDA shall be promptly reviewed, evaluated, and investigated. A complaint that does not represent an event required to be reported shall be reviewed and evaluated to determine whether investigation is necessary; 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, the establishment shall maintain a record that includes the reason no investigation was made, and the name of the individual responsible for the decision not to investigate.

4. Subpart E, consisting of §§ 1271.330 through 1271.370, is added to part 1271 to read as follow:

Subpart E—Additional Requirements for Establishments Described in § 1271.10

Sec.
1271.330 Applicability.
1271.350 Reporting.
1271.370 Labeling and claims.

Subpart E—Additional Requirements for Establishments Described in § 1271.10

§ 1271.330 Applicability

The provisions set forth in this subpart are applicable only to human cellular and tissue-based products described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act (the PHS Act) and the regulations in this part, and to the establishments that manufacture those products. Human cellular and tissue-based products described in § 1271.15 and regulated as drugs, devices, and/or biological products under the act and/or section 351 of the PHS Act, and the establishments that manufacture those products, are not subject to the regulations set forth in this subpart.

§ 1271.350 Reporting.

(a) *Adverse reaction reports.* (1) Any establishment that receives information about an adverse reaction, regardless of source, shall review the information to determine whether the adverse reaction is required to be reported. The establishment shall report any adverse reaction involving the transmission of a communicable disease, product contamination, or failure of the product's function or integrity if the adverse reaction:

(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. Each report shall be submitted on an FDA Form-3500A to the address in paragraph (a)(4) of this section within 15 calendar days of initial receipt of the information.

(2) The establishment shall promptly investigate all adverse reactions that are subject of these 15-day reports and shall submit follow-up reports within 15 calendar days of the receipt of new information or as requested by FDA. If additional information is not obtainable, a follow-up report may be required that describes briefly the steps taken to seek additional information and the reasons why it could not be obtained.

(3) Copies of the reporting form (FDA-3500A) may be obtained from the Center for Biologics Evaluation and Research (see address in paragraph (a)(4) of this section). Additional supplies of the form may be obtained from the Consolidated Forms and Publications Distribution Center, 3222 Hubbard Rd., Landover, MD 20785.

(4) The establishment shall 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 product deviations.* (1) Any establishment that becomes aware of a product deviation in the manufacture of a distributed human cellular or tissue-based product shall immediately determine whether the product deviation is of the type that could reasonably be expected to lead to a reportable adverse reaction and, if it is, shall report the product deviation to the address in paragraph (b)(3) of this section as soon as possible.

(2) Each report shall contain a description of the product deviation and information on all corrective actions that have been or will be taken in response to the product deviation (e.g., recalls).

(3) Each report of a product deviation shall be reported 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.

(c) *Records.* Reports and investigations required under this section shall be documented and records shall be maintained.

§ 1271.370 Labeling and claims.

(a) *Label information and accompanying materials.* (1) Each human cellular or tissue-based product made available for distribution shall be labeled clearly and accurately.

(2) The following information shall appear on the product label:

(i) Name and address of the establishment that determines that the product meets release criteria and makes the product available for distribution;

(ii) Description of the type of product; and

(iii) Expiration date, if any.

(3) The following information shall appear either on the product label or package insert:

(i) Storage temperature;

(ii) Warnings, where appropriate; and

(iii) Instructions for use.

(b) *Claims.* (1) All labeling, advertising, and promotional materials for a human cellular or tissue-based product shall be clear, truthful, and balanced in all respects, and may not be false or misleading in any particular.

(2) A labeling claim or promotional materials regarding the therapeutic or clinical outcome of a human cellular or tissue-based product (other than reconstruction, replacement, repair, or supplementation of cells or tissue) is considered a claim for a use other than a homologous use, as defined in § 1271.3(d), and the product, including labeling, shall be regulated under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act.

5. Subpart F, consisting of §§ 1271.390 through 1271.440, is added to part 1271 to read as follows:

Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10

Sec.
1271.390 Applicability.
1271.400 Inspections.
1271.420 Human cellular and tissue-based products 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 human cellular and tissue-based products described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act (the PHS Act) and the regulations in this part, and to the establishments that manufacture those products. Human cellular and tissue-based products described in § 1271.15 and regulated as drugs, devices, and/or biological products under the act and/or section 351 of the PHS Act, and the establishments that manufacture those products, are not subject to the regulations set forth in this subpart.

§ 1271.400 Inspections.

(a) An establishment subject to this part as described in § 1271.10, including any location performing contract services, shall permit an authorized representative of the Food and Drug Administration (FDA) to make at any reasonable time and in a reasonable manner such inspection of the establishment, including but not limited to its facilities, equipment, processes, products, procedures, labeling, and records, as may be necessary in the judgment of such representative to determine compliance with the provisions of this part. Such inspection may be made with or without notice and will ordinarily be made during regular business hours.

(b) The frequency of inspection will be at the agency's discretion.

(c) FDA's representative 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 the representative deems necessary.

(d) FDA's representative may review and copy any records required to be kept under this part and may take photographs or make videotapes.

(e) The public disclosure of records containing the name or other positive identification of donors or recipients of human cellular or tissue-based products will be handled in accordance with FDA's procedures on disclosure of information as set forth in part 20 of this chapter.

§ 1271.420 Human cellular and tissue-based products offered for import.

(a) When a human cellular or tissue-based product is offered for entry, the importer of record shall notify the director of the district of the Food and Drug Administration (FDA) having jurisdiction over the port of entry through which the product 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.

(b) A human cellular or tissue-based product offered for import shall be held intact, under conditions necessary to maintain product function and integrity and prevent transmission of communicable disease, until it is released by FDA.

§ 1271.440 Orders of retention, recall, destruction, and cessation of manufacturing.

(a) Upon an agency finding that a human cellular or tissue-based product or an establishment is in violation of the regulations in this part, an authorized Food and Drug Administration (FDA) representative may take one or more of the following actions:

(1) Serve upon the person who distributed the human cellular or tissue-based product a written order that the product be recalled and/or destroyed, as appropriate, and upon persons in possession of the product that the product shall be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the product is confirmed;

(2) Take possession of and/or destroy the violative human cellular or tissue-based product; or

(3) Serve upon the establishment an order to cease manufacturing until compliance with the regulations of this part has been achieved.

(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 human cellular or tissue-based product 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 human cellular or tissue-based product shall not distribute or dispose of the product in any manner except to recall and/or destroy the product consistent with the provisions of the order, under the supervision of an authorized FDA representative.

(2) In lieu of paragraph (c)(1) of this section, other arrangements for assuring the proper disposition of the human cellular or tissue-based product may be agreed upon by the person receiving the written order and an authorized official of FDA. Such arrangements may include, among others, providing FDA with records or other written information that adequately assure that the human cellular or tissue-based product has been recovered, processed, stored, and distributed in conformance with this part, and that, except as provided under §§ 1271.65 and 1271.90, the donor of the cells or tissue for the product has been determined to be suitable.

(d) A written order issued under paragraph (a)(3) of this section will specify the regulations with which compliance shall be achieved and will ordinarily specify the particular operations covered by the order. After receipt of an order issued under paragraph (a)(3) of this section, an establishment shall not resume operations without prior authorization of an authorized official of FDA.

(e) 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 a human cellular or tissue-based product under paragraph (a)(2) of this section), the recipient of the written order or prior possessor of such product may request a hearing on the matter in accordance with part 16 of this chapter. An order of destruction will be held in abeyance pending resolution of the hearing request.

Dated: August 29, 2000.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 01–447 Filed 1–5–01; 8:45 am]

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The list will resume when bills are enacted into public law during the next session of Congress. A cumulative list of Public Laws will be published in the **Federal Register** on Tuesday, January 16, 2001.

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S. 2749/P.L. 106–577
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 1999, through January 1, 2000. The CFR volume issued as of January 1, 1999 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 1999, through April 1, 2000. The CFR volume issued as of April 1, 1999 should be retained.

[6] No amendments to this volume were promulgated during the period July 1, 1999, through July 1, 2000. The CFR volume issued as of July 1, 1999 should be retained..